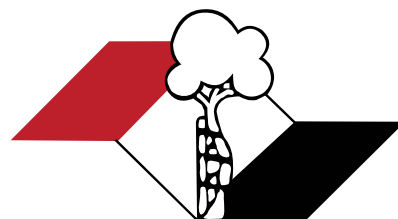


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ISSN 1413-7852

# Acta Ortopédica Brasileira



Volume 31 – Number 1 – Year 2023

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Especial

# Acta Ortopédica Brasileira



Department of Orthopedics and Traumatology, Faculdade de Medicina da Universidade de São Paulo (DOT/FMUSP), São Paulo, SP, Brazil

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(Reviewed April 2022)

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Types of study				
Level	Therapeutic Studies Investigating the Results of Treatment	Prognostic Studies – Investigating the Effect of a Patient Characteristic on the Outcome of Disease	Diagnostic Studies – Investigating a Diagnostic Test	Economic and Decision Analyses – Developing an Economic or Decision Model
I	High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	High quality prospective study <sup>d</sup> (all patients were enrolled at the same point in their disease with ≥80% of enrolled patients)	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)	Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses
	Systematic review <sup>b</sup> of Level RCTs (and study results were homogenous <sup>c</sup> )	Systematic review <sup>b</sup> of Level I studies	Systematic review <sup>b</sup> of Level I studies	Systematic review <sup>b</sup> of Level I studies
II	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective <sup>f</sup> study	Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)	Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses
	Prospective <sup>d</sup> comparative study <sup>g</sup>	Untreated controls from an RCT	Systematic review <sup>b</sup> of Level II studies	Systematic review <sup>b</sup> of Level II studies
	Systematic review <sup>b</sup> of Level II studies or Level I studies with inconsistent results	Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% followup)		
		Systematic review <sup>b</sup> of Level II studies		
III	Case control study <sup>g</sup>	Case control study <sup>g</sup>	Study of non consecutive patients; without consistently applied reference “gold” standard	Analyses based on limited alternatives and costs; and poor estimates
	Retrospective <sup>f</sup> comparative study <sup>g</sup>		Systematic review <sup>b</sup> of Level III studies	Systematic review <sup>b</sup> of Level III studies
	Systematic review <sup>b</sup> of Level III studies		Case-control study	
			Poor reference standard	
IV	Case series <sup>h</sup>	Case series		Analyses with no sensitivity analyses
V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

<sup>a</sup> A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

<sup>b</sup> A combination of results from two or more prior studies.

<sup>c</sup> Studies provided consistent results.

<sup>d</sup> Study was started before the first patient enrolled.

<sup>e</sup> Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.

<sup>f</sup> The study was started after the first patient enrolled.

<sup>g</sup> Patients identified for the study based on their outcome, called “cases” eg, failed total arthroplasty, are compared with patients who did not have outcome, called “controls” eg, successful total hip arthroplasty.

<sup>h</sup> Patients treated one way with no comparison group of patients treated in another way.

**ORIGINAL ARTICLE****CHILD ORTHOPEDICS**

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Thiago Danilo Rodrigues de Almeida, Paulo Roberto Carvalho Carvalho, Brauner de Souza Cavalcanti, Gabriel Guerra Cordeiro, Caio César Barbosa Siqueira, Vinicius Gueiros Buenos Aires, Eptácio Leite Rolim Filho

DOI: <http://dx.doi.org/10.1590/1413-785220233101e256215>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e259040>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e259041>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e257850>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e252977>

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Muhsin Dursun, Guray Altun, Murat Ozsahin

DOI: <http://dx.doi.org/10.1590/1413-785220233101e252916>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e253655>



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DOI: <http://dx.doi.org/10.1590/1413-785220233101e258926>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e259011>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e250368>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e239997>

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DOI: <http://dx.doi.org/10.1590/1413-785220233101e255572>

**REVIEW ARTICLE**

**HIP**

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*Jaime José Morales de Cano, Estela Trias*

DOI: <http://dx.doi.org/10.1590/1413-785220233101e256913>

# EVALUATION OF TENOTOMY IN THE HIP SUBLUXATION TREATMENT OF CHILDREN WITH ZIKA SYNDROME

## AVALIAÇÃO DA TENOTOMIA NO TRATAMENTO DA SUBLUXAÇÃO DO QUADRIL DE CRIANÇAS COM ZIKA

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### ABSTRACT

**Objective:** Evaluate the efficacy and effects of releasing the muscles of subluxated hips of patients with SCZ. **Methods:** This is a retrospective study with 29 patients with subluxation of the hip, corresponding to 55 hips operated in a public hospital in Recife, Brazil. Preoperative femoral head migration (PM) percentages were evaluated and compared with 6- and 12-month postoperative results. **Results:** Twenty-nine patients were eligible, representing 55 hips evaluated. 19 were female (65.5%), with a mean age of 31.45 months (ranging from 23 to 42 years). 19 patients were GMFCS level V (65.5%), 34.5% were level IV, and 20 of the 29 patients (69%) had no complications. The PM had an absolute reduction of 11.6% (GMFCS IV) and 13.31% (GMFCS V) in the first six months. After 12 months, there was a regression of MP of 7.14% (GMFCS V) and 11.25% (GMFCS IV) compared to preoperative values, with no significant statistical difference among MP values presented between 6 and 12 months after surgery. **Conclusions:** The surgery was effective in PM regression during the analyzed period and presented a low complication rate. **Level of Evidence III; Comparative retrospective study.**

**Keywords:** Zika virus. Hip dislocation. Femoral head. Soft tissue release.

### RESUMO

**Objetivo:** Avaliar a eficácia e os efeitos da liberação das musculaturas de quadris subluxados de pacientes com SCZ. **Métodos:** Trata-se de um estudo do tipo retrospectivo com 29 pacientes CZS com subluxação do quadril, correspondendo a 55 quadris operados em um hospital público de Recife, Brasil. Foram avaliados os percentuais migratórios da cabeça femoral (PM) no pré-operatório e comparados com os resultados pós-operatórios de 6 e 12 meses. **Resultados:** Foram elegíveis 29 pacientes, representando 55 quadris avaliados. 19 eram do sexo feminino (65,5%), com média de idade de 31,45 meses (variando de 23 a 42 anos). 19 pacientes eram GMFCS nível V (65,5%), 34,5% eram nível IV e 20 dos 29 pacientes (69%) não apresentaram complicações. O PM teve redução absoluta de 11,6% (GMFCS IV) e de 13,31% (GMFCS V), nos primeiros seis meses. Após 12 meses, houve regressão do PM de 7,14% (GMFCS V) e de 11,25% (GMFCS IV) em relação aos valores pré-operatórios, sem diferença estatística entre os valores do PM apresentados entre 6 e 12 meses da cirurgia. **Conclusões:** A cirurgia foi eficaz em regredir o PM no período analisado e apresentou uma baixa taxa de complicações. **Nível de Evidência III; Estudo retrospectivo comparativo.**

**Descritores:** Zika vírus. Luxação do quadril. Cabeça femoral. Liberação de Tecidos Moles.

**Citation:** Almeida TDR, Carvalho PRC, Cavalcanti BS, Cordeiro GG, Siqueira CCB, Buenos Aires VG, Rolim Filho EL. Evaluation of tenotomy in the hip subluxation treatment of children with Zika syndrome. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 4. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Congenital Zika syndrome (CZS) is a Brazilian public health problem<sup>1</sup>, it presents a distinct pattern of birth defects and disabilities resulting from intrauterine Zika Virus (ZIKV)<sup>2</sup> infection, may have orthopedic<sup>3</sup> and neurological repercussions<sup>3,4</sup> which include important spastic hypertonia<sup>5,6</sup> with early hip dislocation, besides other systemic changes<sup>7-9</sup>. The motor impairment in these children is mostly grave. According to Melo<sup>6</sup>, the gross motor function classification system (GMFCS)<sup>10</sup> can be used in CZS, with 81% of

children presenting with level V<sup>6</sup>. As in cerebral palsy (CP), they are prone to hip dislocation due to spasticity. This should be treated or avoided, regardless of the gait prognosis, as it has a negative impact on patients' quality of life<sup>11-13</sup>.

In subluxated hips, soft tissue release is a surgical procedure used in patients with CP, with proven effectiveness in preventing spastic dislocation of the hips<sup>14-17</sup>, especially in young patients, under 4 years old. In many cases bone reconstructive surgery may be necessary<sup>14,18</sup>, but it is usually reserved for patients over 4 years old<sup>15,19</sup>.

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Universidade Federal de Pernambuco, Hospital Getúlio Vargas, Hospital Maria Lucinda, Recife, Brazil. Correspondence: Thiago Danilo Rodrigues de Almeida. Rua Luiz Barbalho, 142, Recife, PE, Brazil. 50070-120. [thiagodanillo@msn.com](mailto:thiagodanillo@msn.com)

Article received on 09/10/2021, approved in 02/18/2022.



In our study all our patients were younger than 4 years old, therefore unfit to undergo osseous reconstructive surgery.

However, there are no studies evaluating the effectiveness of soft tissue release in hip subluxation of CZS patients. Patients with CZS are currently being treated, in some Brazilian medical centers, according to the guidelines for CP patients.

In a pioneering way, has been evaluated the efficacy of soft tissue release from the hip in CZS patients with subluxation in delaying natural progression of spastic hip dislocation. These patients were assessed after a follow-up period up to 12 months. This is a preliminary study aimed to evaluate the efficacy of tenotomies in the hips of CZS patients under 4 years old, who presented hip subluxation, using the migration percentage of the femoral head (MP) on the pelvic radiograph, according to Reimers index method<sup>20</sup>, as a measure to assess the outcome of subluxation within a year after surgery. New studies will be conducted to assess these long-term effects.

## MATERIAL AND METHODS

The study population comprised a consecutive series of forty-two children with CZS, from 23 to 42 months old, who underwent surgery between January 2017 and December 2018, in a public hospital in Recife, Pernambuco state, Brazil, being submitted to open tenotomy to release the hip adductors and of the iliopsoas, for treating spastic subluxation of the hip. Postoperatively, all were included in motor rehabilitation programs after a period of 30 to 60 days of use a hip abduction orthosis. The board of the Research Ethics Committee from the Federal University of Pernambuco approved this study, waiving the use of informed consent (CAAE: 87564218.2.0000.5208). A retrospective review of the results in this group was performed in two different periods, defined at six and twelve months after surgery. Patients in this study had to meet the following inclusion criteria: have clinical and laboratory confirmation of CZS; present at least one hip at risk of dislocation prior to surgery (defined as an MP of  $\geq 30\%$  or hip abduction of  $30^\circ$  or less); have medical records correctly filled in, with clinical and radiographic data (pre and postoperative); and have not undergone previous hip surgeries.

The study was retrospective, observational, and longitudinal. Preoperative, six-month and twelve-month postoperative radiographs were reviewed to determine MP. Patients' medical records were reviewed to determine GMFCS motor level record, outpatient status, age at surgery, hip abduction, and surgical history of repeated soft tissue release or bone surgery on the hip. Data was collected between May 15, 2019, and August 30, 2020. Forty-two children were selected for the study. All 42 patients had CZS with subluxation of at least one hip and surgical indication signed by a pediatric orthopedist. Of these, 13 children were excluded: 5 for partial or total loss of data from their medical records; 2 for not having the laboratory confirmation of CZS's diagnosis in their medical records; and 6 for not having radiographic data stored in their medical records, or by presenting inadequate radiographs for radiographic index evaluation. Ultimately 29 patients met the inclusion criteria. All patients were unable to walk, 19 patients (65.5%) were female, and the others were male. The patients were, on average, 31.45 months-old at the time of surgery (ranging from 23 to 42 months). The majority had GMFCS level V (65.5%).

All patients underwent surgery with the same team of orthopedists, following American Academy of Cerebral Palsy and Developmental Medicine (AACPDM)<sup>21</sup> recommendations to classify the patient's risk of having a hip dislocated, and were guided by the existing criteria for CP used by Presedo<sup>15</sup> and other authors<sup>14,16,17,20,22</sup> to indicate the surgeries. Surgical indications were based on the patient's age, degree of hip abduction in flexion, and percentage of hip migration (MP  $\geq 30\%$  or hip abduction of  $30^\circ$  or less)<sup>21</sup>. The surgical procedure comprised tenotomy of the long adductor, of the short adductor, iliopsoas and complete myotomy of the gracilis in all patients.

This procedure was performed on both hips in twenty-six of the twenty-nine patients. Asymmetric procedures, defined as operations in which the soft-tissue release was performed unilaterally, were carried out in three patients. In total, fifty-five hips were submitted to this method. Hip migration percentage (MP) was used to determine the degree of hip subluxation radiographically, according to parameters described by Reimers<sup>20</sup>. To determine the MP, anteroposterior (AP) radiographs of the pelvis were used, taken up to 30 days before surgery and in the postoperative periods of 6 and 12 months, performed with the patient in supine position, femurs in neutral abduction-adduction in relation to the pelvis, and the patella facing forward. (Figure 1)

The same investigator analyzed all the patients' radiographic indexes. Each radiograph received a random identification code that did not allow the evaluator, during the analysis, to identify the patient to which they belonged, and made no reference to the period when they were taken (preoperative, 6 months or 12 months postoperative).

## Statistical Analysis

Patients' clinical data, such as age at the time of surgery and complication rate, were analyzed descriptively, using absolute frequencies and percentages for categorical variables, and measures such as mean and standard deviation (mean  $\pm$  SD) for numeric variables. In MP evaluation, in pre and postoperative periods, a category comparison was made in relation to the numerical variables (scale scores) and the following tests were used: Student's t-test or Mann-Whitney for two categories, and F (ANOVA) or Kruskal-Wallis for more than two categories. When comparing pairs of assessments on numerical variables, paired Student's t-test or paired Wilcoxon tests were used. The difference between values obtained in the scale means and reference values was verified using a one sample t-test. Student's t-tests were used for equal variances. Student's t-test for unequal variances, paired Student's t-test, F (ANOVA) and Pearson's correlation occurred in situations where the data (or the difference between evaluations) presented a normal distribution. Mann-Whitney, paired Wilcoxon and Kruskal-Wallis tests were used due to the absence of normality, sample size inferior to 6 cases or ordinal scale. The verification of normality was performed by the Shapiro-Wilk test and equality of variances by the Levene F test. The level of significance was set at  $p \leq 0.05$ .

## RESULTS

Twenty-nine CZS patients with spastic hip subluxation underwent soft tissue release procedures, in a total of 55 hips. Patients were, on average, 31.45 months old at the time of the surgery (standard



**Figure 1.** Anteroposterior radiography of the pelvis with migration percentages of the femoral head measurement.



deviation of 5.34 months, median of 30.00 and range from 23 to 42 months). Table 1 shows that 51.7% were 24 to 30 months old, 20.7% were 31 to 36 months old, and 27.6% were 37 to 42 months old. Regarding the GMFCS classification, 65.5% presented level V and 34.5% were level IV, no patient had GMFCS I, II or III. 69% patients did not report complications, but 31.0% of them had some complication, the most prevalent of which was irritability (13.8%), followed by genital edema (10.3%) and contracture of hips in abduction (10.3%). Seizures and fever had reported frequencies of 6.9%, pain was reported in 3.4%. There was no record of suture dehiscence, postoperative infection, vascular or nerve injury or death resulting from surgery. (Table 1)

All children had at least one hip with subluxation, defined as a migration percentage  $\geq 30\%$ . Of the 29 patients who underwent surgery, 26 were operated on both hips and 3 were operated unilaterally, totaling 55 evaluated hips. Table 2 shows the MP (in %), according to the GMFCS, and the comparative evaluations between pre (operative) and 6 months (post-operative), pre and 12 months, and 6 months to 12 months. (Table 2)

According to results in Table 2, it can be noted that the only significant differences between the categories of GMFCS IV and V occurred in the Reimers index in pre and 6 month evaluations and, in these variables, the averages were found to be correspondingly higher among GMFCS V patients than in level IV patients (53.00 x 37.80 in the preoperative period and 39.69 x 26.20 in the 6 month evaluation). The averages were correspondingly higher in the pre rather than the 6 month assessment and in the pre rather than the 12 month assessment, with significant differences between pre and 6 month assessment in group IV and pre and 6 month assessment in group V. There were no significant differences ( $p > 0.05$ ) between 6 and 12 months.

## DISCUSSION

The analysis of 29 CZS patients in this report revealed an early tendency to hip dislocation in CZS (average age of 31,45 months) may be related to the grave profile of spasticity in patients with the

**Table 2.** Comparative statistics on MP according to GMFCS and operative period.

Variable	GMFCS		p-value
	IV	V	
	Mean $\pm$ SD (median)	Mean $\pm$ SD (median)	
<b>MP (in%)</b>			
<b>Pre x 6 months</b>			
Pre (n = 39)	37.80 $\pm$ 11.25 (37.00)	53.00 $\pm$ 17.76 (50.00)	$p^{(1)} = 0.016 *$
6 months (n = 39)	26.20 $\pm$ 11.92 (30.00)	39.69 $\pm$ 11.25 (40.00)	$p^{(1)} = 0.003 *$
p-value	$p^{(4)} = 0.013 *$	$p^{(5)} < 0.001 *$	
Absolute difference	11.60 $\pm$ 8.22 (9.00)	13.31 $\pm$ 16.43 (8.00)	$p^{(2)} = 0.489$
Difference %	32.41 $\pm$ 21.75 (26.72)	21.27 $\pm$ 19.75 (21.05)	$p^{(2)} = 0.126$
<b>Pre x 12 months</b>			
Pre (n = 41)	48.42 $\pm$ 14.52 (46.00)	48.59 $\pm$ 14.17 (47.00)	$p^{(1)} = 0.973$
12 months (n = 41)	37.17 $\pm$ 15.13 (31.50)	41.45 $\pm$ 18.41 (39.00)	$p^{(1)} = 0.481$
p-value	$p^{(4)} = 0.015 *$	$p^{(4)} = 0.052$	
Absolute difference	11.25 $\pm$ 13.62 (9.00)	7.14 $\pm$ 18.94 (4.00)	$p^{(1)} = 0.500$
Difference %	20.97 $\pm$ 25.17 (20.53)	11.23 $\pm$ 37.23 (10.00)	$p^{(1)} = 0.413$
<b>6 months x 12 months</b>			
6 months (n = 25)	35.00 $\pm$ 7.75 (33.00)	41.48 $\pm$ 12.36 (44.00)	$p^{(2)} = 0.413$
12 months (n = 25)	31.25 $\pm$ 7.46 (29.00)	39.90 $\pm$ 15.39 (38.00)	$p^{(2)} = 0.265$
p-value	$p^{(5)} = 0.125$	$p^{(5)} = 0.807$	
Absolute difference	3.75 $\pm$ 0.50 (4.00)	1.57 $\pm$ 11.00 (0.00)	$p^{(2)} = 0.298$
Difference %	10.92 $\pm$ 1.65 (11.24)	1.78 $\pm$ 30.13 (0.00)	$p^{(2)} = 0.207$

(\*) Significant difference at the level of 5.0%. (1) By the Student's t-test with equal variances. (2) By the Mann-Whitney test. (3) By the Student's t-test with unequal variances. (4) By the paired Student's t-test. (5) By the paired Wilcoxon test.

syndrome (usually GMFCS V). Despite a reportedly high failure rate in isolated soft tissue releases<sup>22</sup>, the patient population had a very young age profile, therefore the utilization of soft tissue releases, even in patients with a high MP ( $> 50\%$ ), was preferable to reconstructive bone surgery, which may be performed with less surgical risk posteriorly if indicated. In our sample, all patients presented either GMFCS level V (65.5%) or level IV (34.5%). This profile of more grave involvement in CZS was also observed by Melo et al., who described in their sample a predominance of motor level V (GMFCS) in 81% of the children<sup>6</sup>. Another factor that could have influenced the early hip displacement in these patients may be the fact that, in the sample, no child was able to walk<sup>12</sup>.

The main reported surgical complication was the presence (or worsening) of irritability in the postoperative period (13.8%). The presence of irritability, defined by increased crying, is reported in CZS patients<sup>5,6</sup>, even those who have not undergone surgical procedures.

Evaluating the MP before and after 6 months of surgery, it was observed that the procedure was effective in regressing the MP, similarly in both level IV and level V groups. In patients with GMFCS IV (mean preoperative MP of 37.8%), the MP decreased to 26.2%. In GMFCS V patients, the average MP was 53% and decreased to 39.69%.

According to Presedo et al., who defined in their study as satisfactory results those which, after the soft tissue release, had MP  $\leq 39\%$  and unsatisfactory those with MP  $\geq 40\%$ , the result presented in patients with CZS after 6 months is considered reasonably satisfactory (migration from 25% to 39%)<sup>15</sup>.

In the GMFCS V group, the MP regressed from 48.59% to 41.45%, 12 months after surgery. The MP 41.45% (GMFCS V) and 37.17% (GMFCS IV) is satisfactory if analyzed by the most current criteria used by Terjesen et al.<sup>16</sup>, who considers the surgery to be satisfactory

**Table 1.** Demographic profile of the analyzed sample.

Variable.	n	%
Total	29	100.0
<b>Age group (months)</b>		
24 to 30	15	51.7
31 to 36	6	20.7
37 to 42	8	27.6
<b>Sex</b>		
Male	10	34.5
Female	19	65.5
<b>GMFCS</b>		
IV	10	34.5
V	19	65.5
<b>Occurrence of complications</b>		
Yes	9	31.0
No	20	69.0
<b>Complications</b>		
None	20	69.0
Irritability	4	13.8
Edema	3	10.3
Abduction contracture	3	10.3
Convulsion	2	6.9
Fever	2	6.9
Pain	1	3.4

("successful") when the MP in the last follow-up was <50%. Myongsu Ha et al.<sup>24</sup> had a greater regression in the MP, in which the surgery reduced the MP from 62% to 37,9% on average.

Shore et al.<sup>22</sup> defined as a good result for soft tissue surgery the absence of revision surgery and a MP <50% at the last follow-up. 27% in our group (12 of the 44 hips evaluated in 12 months) had an unsatisfactory MP (50% or more), but the group had an average MP of 41.45% (GMFCS V) and 37.17% (GMFCS IV) in the last follow-up (12 months). Other researchers had not acceptable results: in 48% patients from Nikolaos Kiapikos et al. (GMFCS IV and V)<sup>25</sup>, 40% from Presedo et al.<sup>15</sup>, 58% from Turker and Lee<sup>23</sup>, and 75% of Shore<sup>22</sup> et al. patients, they did not have satisfactory results by the same criteria. We had no cases of revision surgery.

Examining the MP before and 12 months after surgery, it is observed in the GMFCS IV group that the average MP after 12 months was 37.17%, showing an absolute reduction of 11.25, similar to the absolute decrease presented in the 6 month postoperative period (11.60), indicating that, in relation to the preoperative period, there was a reduction in MP, but comparing the 6 and 12 month postoperative periods, there was no statistical difference in the hip MP of these patients ( $p = 0.125$  and absolute difference of 3.75), indicating a stabilization in the hip MP between 6 and 12 months after the surgery. Similarly to level IV, the level V group also presented a tendency towards stabilization in the MP between 6 and 12 months after

surgery, with an absolute difference of only 1.57 and a percentage of 1.78%, showing no statistical difference between values measured at twelve and six months postoperative ( $p = 0.807$ ).

The present study contributes to understanding the soft tissue surgery in the treatment applied in hip dislocation in CZS, contributing to assist orthopedists in the treatment of these patients. In our population, with a rare syndrome, we have had as limitation a small sample size. To expand this sample, we evaluated individualized results by hip. Another limiting factor was a short follow-up, as future perspectives, we intend to do new studies with longer follow-ups to determine if the MP regression persists more than 12 months after surgery and conduct new studies evaluating the results of reconstructive surgeries in dislocated hips of the SCZ.

## CONCLUSION

In conclusion, not all patients analyzed was a satisfactory final MP, but the surgery was effective in causing regression in MP, both in patients with GMFCS IV and V, with a significantly greater reduction in the first 6 months after the procedure, showing better results in level IV patients during this period. There was a tendency to stabilize the average MP obtained between 6 and 12 months after surgery. The surgery presented a low rate of complications in SCZ patients.

**AUTHORS' CONTRIBUTION:** TDRA: conception, literature review, work design, data acquisition and interpretation, article writing. ELRF: conception, guidance, work design, interpretation of data, article review. PRCC: guidance, data interpretation, article review. BSC: data acquisition and interpretation, article writing. VGBA: data acquisition, article writing. CCBS: contribution: data acquisition, article writing. GGC: data acquisition, article writing.

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# MODIFIED SALTER PELVIC OSTEOTOMY FOR THE DDH TREATMENT

## OSTEOTOMIA PÉLVICA DE SALTER MODIFICADA PARA TRATAMENTO DE DDH

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### ABSTRACT

**Objective:** Three pelvic osteotomies (Salter, Dega, Pemberton) are widely used in walking patients under seven years old for DDH treatment. We've proposed a modified Salter Pelvic Osteotomy (SPO), which has the advantages of the abovementioned osteotomies. **Methods:** Short- and mid-term results were assessed in 19 patients after the modified SPO application. Patients were examined before and after the surgery, at 6 months postoperatively, and at follow-up. **Results:** Acetabular Index (AI) before the surgery was  $39.5 \pm 7^\circ$ ; after the surgery -  $24.4 \pm 5.5^\circ$ , at 6 months -  $20.4 \pm 5^\circ$  (9-28), at follow-up -  $14.5 \pm 4^\circ$ ; AI correction -  $14.9 \pm 5.5^\circ$ . Lateral Centre-Edge Angle at follow-up -  $22.7 \pm 4.7^\circ$ . Clinical results at follow-up were I / II McKay grade in 18 patients (94.7%); radiological results were I / II Severin class in 18 patients (94.7%). **Conclusion:** Modified SPO improves the FH coverage in any direction; results after modified SPO are excellent and good in most patients. **Level of Evidence IV; Case Series.**

**Keywords:** Developmental Dysplasia of the Hip. Pelvic Region. Osteotomy. Evaluation of Results of Therapeutic Interventions.

### RESUMO

**Objetivo:** Três osteotomias pélvicas (Salter, Dega, Pemberton) são amplamente utilizadas em pacientes ambulatoriais com menos de sete anos de idade para tratamento com DDH. Foi proposta a Osteotomia Pélvica de Salter modificada (SPO), que apresenta as vantagens das osteotomias acima mencionadas. **Métodos:** Os resultados de curto e médio prazo foram avaliados em 19 pacientes após a aplicação da SPO modificada. Os pacientes foram examinados antes e após a cirurgia, aos 6 meses de pós-operatório, e no acompanhamento. **Resultados:** O Índice Acetabular (IA) antes da cirurgia foi de  $39,5 \pm 7^\circ$ ; após a cirurgia -  $24,4 \pm 5,5^\circ$ , aos 6 meses -  $20,4 \pm 5^\circ$  (9-28), no acompanhamento -  $14,5 \pm 4^\circ$ ; correção da IA -  $14,9 \pm 5,5^\circ$ . Ângulo Lateral do Centro-Edge Angle no acompanhamento -  $22,7 \pm 4,7^\circ$ . Os resultados clínicos no acompanhamento foram I / II grau McKay em 18 pacientes (94,7%); os resultados radiológicos foram I / II classe Severin em 18 pacientes (94,7%). **Conclusão:** A SPO modificada melhora a cobertura de FH em todos os sentidos; os resultados após a SPO modificada são excelentes e bons na maioria dos pacientes. **Nível de Evidência IV; Série de casos.**

**Descritores:** Displasia do Desenvolvimento do Quadril. Osteotomia. Pelve. Avaliação de Resultado de Intervenções Terapêuticas.

**Citation:** Vasyi S, Viktor F. Modified salter pelvic osteotomy for the DDH treatment. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 4. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Developmental Dysplasia of the Hip (DDH) is one of the most common pathologies of the hip joint in children.<sup>1</sup> The age of DDH detection is critical - non-surgical treatment is effective only in case of early diagnosis (in non-walking patients).<sup>2</sup> In case of DDH late detection (in walking patients) or after the failure of non-surgical treatment (in case of residual acetabular dysplasia or femoral head redislocation), surgical treatment is indicated.<sup>3</sup> There are different types of surgeries for DDH management, but the best results were observed after pelvic osteotomies application.<sup>4</sup> Three different pelvic osteotomies (Salter, Dega, Pemberton) are commonly used in patients with DDH younger than 7 years old.<sup>5</sup> Each of these osteotomies has certain advantages and disadvantages. Thus, Salter osteotomy is easier to perform, but it is possible to

improve only the anterolateral femoral head (FH) coverage and provides lower acetabular deformity correction degree compared to Pemberton and Dega osteotomies.<sup>6,7</sup> Using Dega osteotomy it is possible to improve the FH coverage in all directions and to achieve a higher correction degree but is technically demanding in patients under 4 years (due to the smaller iliac bone thickness).<sup>7</sup> Pemberton pelvic osteotomy also allows to achieve higher correction degree, but using it it is possible to improve only the anterolateral FH coverage; another disadvantage after this surgery is a possible triradiate cartilage injury.<sup>6,8,9</sup> Today it is well-known that DHH presents itself not purely as an anterolateral acetabular deficiency; three types of acetabular deformities were found.<sup>10</sup> Thus, there is a need for a pelvic osteotomy that would be able to improve FH coverage in all directions. Other

All authors declare no potential conflict of interest related to this article.

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Article received on 12/10/2021, approved on 05/04/2022.





prerequisites for pelvic osteotomy are: to ensure a sufficient level of acetabular deformity correction; to be easy to perform regardless of the patient's age; have no risk of triradiate cartilage injury. In our hospital, we use a modified Salter Pelvic Osteotomy (SPO) that meets the abovementioned requirements.

The purposes of this article were:

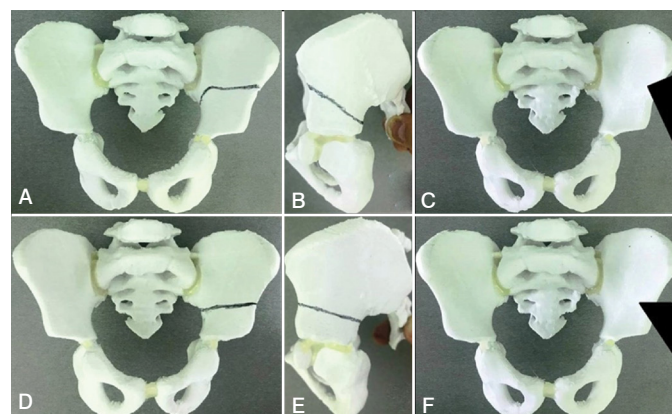
1. to describe our modification of SPO
2. to show short and middle-term results after this technique

## METHODS

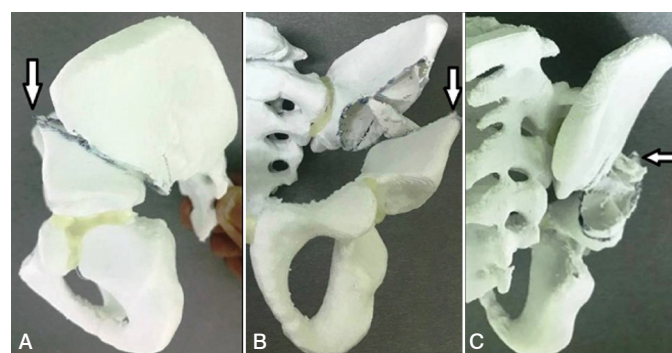
Institutional ethics board committee approval (protocol N° 4 dated 10.12.2021) was obtained for publishing the results of this investigation.

In our institution modified SPO is used from 2015. It is applied in patients older than 2 years old with acetabular dysplasia (acetabular index(AI) values  $\geq 30^\circ$ ); the upper age limit for this technique was 6 years old.

The differences of our SPO modification from the classically described one<sup>11</sup> are the following: 1) a curved line of the osteotomy going horizontally up to the terminal line, then it turns downwards (towards the top of the greater sciatic notch) – Figure 1, A/D; 2) more proximal start point of the osteotomy line – Figure 1, B/E; 3) chisel's blade outer side is turned at  $45^\circ$  upward laterally (according to the principle of Dega pelvic osteotomy) – Figure 1, C/F. The abovementioned features of our modification are shown in Figure 1. This modified SPO allows to improve the FH coverage in all directions (due to the curved osteotomy line - see Figure 2) and achieve a higher degree of AI correction (due to the turned chisel blade



**Figure 1.** The differences of our SPO modification from the classically described one. In the upper row (A-C) our modification is shown, in the lower row (D-F) the classically described SPO is shown.



**Figure 2.** FH coverage improvement in anterior (A), posterior (B) and lateral (C) directions during modified SPO according to applied forces (white arrows).

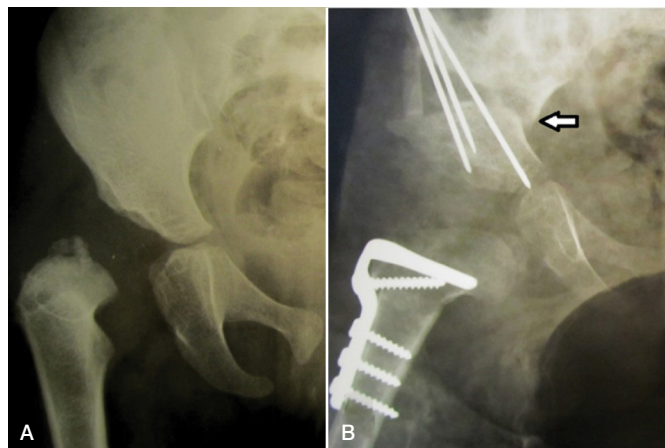
position and, consequently, larger bony contact between iliac bone fragments during acetabular deformity correction). At the same time, our modification is technically easy to perform regardless of the patient's age (since it's itself a complete iliac bone osteotomy and doesn't depend on iliac bone thickness); also, the risk of triradiate cartilage injury is absent (the osteotomy line is far from it). An example of a modified SPO application is shown in Figure 3. To evaluate the results after modified SPO, we've selected 19 patients who underwent this surgery for the period 2015-2020.

Among these patients 18 were girls (94.7%) and 1 was a boy (5.3%); the left hip joint was affected in 12 cases (63.2%), the right - in 7 cases (36.8%); the mean patient's age was  $3.6 \pm 1.5$  years (2-6); the mean follow-up period was  $2.7 \pm 1.6$  years (1-5).

During the pelvic osteotomy, we've improved the FH coverage in that direction where it was a deficiency according to X-rays. The deficit of anterior coverage was estimated according to the anterior center-edge angle (CEA) values on the false profile view (in comparison with "healthy" hip). The posterior FH coverage deficit was determined by comparing the anterior and posterior acetabular walls contours on anterior-posterior X-ray (medial position of the posterior wall relative to the anterior was considered as a posterior acetabular wall deficit - as an analog to posterior wall sign in adults). In the case of both anterior and posterior acetabular deficiency, we've improved the FH coverage in a more defective direction. Lateral FH coverage was routinely improved in all patients.

Additionally to modified SPO in all cases, we've performed femoral varus *derotational osteotomy* (FVDO) to decrease femoral anteversion and valgus deformity. Femoral head open reduction was added in case of impossible concentric closed reduction of the FH; femoral shortening was mandatorily performed in these patients. A combination of FH open reduction, pelvic and femoral osteotomies is known as One-Stage Surgery (OSS).<sup>3</sup> A combination of modified SPO and FVDO was performed in 8 patients (42.1%), OSS was performed in 11 patients (57.9%).

Patients were examined clinically and radiologically before, immediately after surgery, at 6 months postoperatively, at follow-up. Before the surgery, we had determined DDH Tonnis grade and AI values. The day after surgery, we've measured AI values and the amount of AI correction. At 6 months postoperatively, we've measured AI values and detected any signs (if present) of the FH avascular necrosis (AVN). At follow-up, we've determined AI values, Wiberg lateral CEA values; femoral head AVN sequels were assessed



**Figure 3.** An example of modified SPO application in 3 years old female patient. A – before the surgery, B – after Single Stage Surgery. White arrow points to the upper iliac fragment's sharp angle which is due to curved osteotomy (this is a radiological feature of our modification that is absent in classically described SPO).

according to Bucholz and Ogden.<sup>12</sup> Long-term radiological results were evaluated according to Severin classification,<sup>3</sup> long-term clinical results were evaluated according to McKay's criteria.<sup>13</sup> For statistics calculations we've used JASP Team (2020). JASP (Version 0.11.1.0)[Computer software].

## RESULTS

According to DDH Tonnis classification, the II grade was in 6 patients (31.5%), III grade - in 1 patient (5.3%), IV grade - in 12 patients (63.2%).

The AI values before the surgery were  $39.5 \pm 7^\circ$  (30-53).

The next day after surgery AI values were  $24.4 \pm 5.5^\circ$  (15-33).

The amount of AI correction was  $14.9 \pm 5.5^\circ$  (8-28).

At 6 months AI values were  $20.4 \pm 5^\circ$  (9-28). Signs of femoral head AVN were present in 8 patients (42.1%).

At follow-up AI values were  $14.5 \pm 4^\circ$  (6-23); lateral CEA values were  $22.7 \pm 4.7^\circ$  (15-29). Femoral head AVN sequels type I according to Bucholz and Ogden were present in 5 patients (26.3%), type II in 0 patients, type III in 1 patient (5.3%), type IV in 2 patients (10.5%). Clinical results according to McKay's criteria were the following: grade I in 12 patients (63.2%), grade II in 6 patients (31.5%), grade III in 1 patient (5.3%), grade IV in 0 patients (0%). Radiological results according to Severin criteria were the following: class I in 14 patients (73.7%), class II in 4 patients (21%), class III in 1 patient (5.3%), class IV-VI in 0 patients.

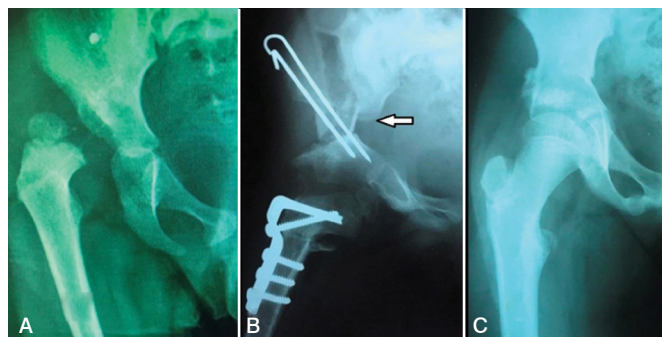
Patients' preoperative characteristics, postoperative clinical and radiological results are presented in Table 1.

The long-term result after the modified SPO application is presented in Figure 4.

Comparison of results after our SPO modification with other authors' results after standard SPO (or their modifications) is presented in Table 2.

## DISCUSSION

Non-surgical management of DDH is effective in case of early diagnosis,<sup>2</sup> but in neglected cases or after non-surgical treatment failure, surgery is mandatory.<sup>3</sup> Pelvic osteotomies are proved to be the most effective surgical option for DDH treatment.<sup>4</sup> Each pelvic osteotomy that is used for DDH treatment in patients younger than 7 years has its strong sides and drawbacks.<sup>5-9</sup> Also, it is known that



**Figure 3.** X-rays of 3 years old female patient. A – before the surgery, B – after the Single Stage Surgery (white arrow points to the upper iliac fragment's sharp angle), C – 4 years postoperatively.

**Table 2.** Comparison of results after modified SPO with other authors' results.

Author (reference)	Results	
	Radiological	Clinical
Esmailnejad-Ganji, S. M. <sup>1</sup>	Severin III - 96.7%; AI - 11.24; CEA - 39.1	Mac-kay III - 94.5%
Gurger, M. <sup>2</sup>	Severin III - 100%; AI - 18.0; CEA - 39.0	Mac-kay III - 100%
Bhuyan BK <sup>3</sup>	Severin III - 83.4%; AI - 21°; CEA - 23.5°	Mac-kay III - 90%
Ahmed, E. <sup>13</sup>	Severin III - 76.8%; AI - 19°; CEA - 26°	Mac-kay III - 80.8%
Da Rocha, V. L. <sup>14</sup>	Severin III - 69.2%; AI - 18.5°	Dutoit (excellent+good) - 92.3%
Chen Q. <sup>15</sup>	Severin III - 83.3%; AI - 21.2°; CEA - 23.5°	Mac-kay III - 90%
Xie X. <sup>16</sup>	Severin III - 97.6%	Mac-kay III - 98.3%
Ahmed K. <sup>17</sup>	Severin III - 90%	Mac-kay III - 89.5%
Bayhan, I. A. <sup>18</sup>	Severin III - 92%; AI - 12.8°; CEA - 30.9°	Mac-kay III - 92%
Morin, C. <sup>19</sup>	Severin III - 96.3%; AI - 12.8°; CEA - 29°	Harris hip score - 94.5
Da Rocha, V. L. <sup>20</sup>	Severin III - 88.9%; CEA - 20.7. 5.02°	Dutoit (excellent+good) - 83.3%
Our modification	Severin III - 94.7%; AI - 14.5. 4°; CEA - 22.7. 4.7°	Mac-kay III - 94.7%

**Table 1.** Patients' preoperative characteristics, postoperative clinical and radiological results (f-up - follow-up; bef - before; aft - after; diff - difference; 6m - 6 months).

Severin	McKay	AVN	CEA	f-up	6m	diff	aft	bef	AI	Tonnis	f-up	surgery	age	side	sex	Nº
1	1	1	28	6	20	10	22	32		2	5	SPO+FVDO	3	L	F	1
1	1		27	12	16	12	22	34		2	2	SPO+FVDO	6	L	F	2
2	2	1	23	16	20	18	25	43		4	1	OSS	3	L	F	3
1	1		29	11	15	14	15	30		2	2	SPO+FVDO	4	L	F	4
1	1	4	26	12	23	17	26	43		4	3	OSS	6	L	F	5
1	1	4	23	13	26	11	26	37		4	3	OSS	6	R	F	6
3	3		15	20	25	22	31	53		4	1	OSS	2	L	F	7
1	1	1	22	9	9	28	15	43		4	2	OSS	4	L	F	8
1	1		26	18	23	9	27	36		4	2	OSS	6	L	F	9
2	2	1	19	18	23	15	33	48		4	1	OSS	4	R	F	10
1	2		20	16	22	15	27	42		4	1	OSS	3	R	F	11
1	2		16	14	21	8	23	31		4	1	SPO+FVDO	2	R	F	12
1	1	3	27	11	25	14	28	42		4	5	OSS	4	L	F	13
1	1		26	14	12	16	15	31		2	4	SPO+FVDO	2	L	F	14
1	1		27	14	16	11	21	32		2	5	SPO+FVDO	2	R	F	15
1	1	1	24	16	22	13	30	43		3	3	SPO+FVDO	3	L	M	16
2	2		15	23	28	9	31	42		4	4	OSS	2	R	F	17
1	1		24	17	24	26	26	52		4	5	OSS	3	R	F	18
2	2		15	15	18	16	20	36		2	1	SPO+FVDO	3	L	F	19



in DDH there is not only a deficiency of anterolateral FH coverage, three types of acetabular deformity were described.<sup>10</sup> Thus, the ideal pelvic osteotomy should improve FH coverage in all directions and should not have known drawbacks. In this paper, we have described our modification of Salter pelvic osteotomy, which meets all the above requirements. Also, the short-term and mid-term results after the modified SPO application were described.

Our modification of SPO differs from the classically described one in that it has a curved line of osteotomy, a more proximal start point of osteotomy and an upward-directed lateral edge of the chisel blade. Short-term and mid-term clinical and radiological results after modified SPO application (follow-up period from 1 to 5 years) were good and excellent in 94.7% of patients; there were no unsatisfactory results. Results after our modification are similar to other authors' results after the application of standard SPO or

their modifications.<sup>1-3,13-20</sup> However, we believe that it is necessary to individually assess the direction of femoral head deficiency and to consider this during preoperative planning.

Shortcomings of this work are: short follow-up period, absence of control group, patients' age is limited to 2-6 years old, no results were described after isolated SPO modification (each patient in this study had additional procedures).

## CONCLUSION

Modified Salter Pelvic Osteotomy make it possible to improve femoral head coverage in any direction in walking patients with DDH under 7 years old; it is technically easy to perform modified SPO independently on the patient's age; this technique provides good Acetabular Index correction; results after modified SPO are excellent and good in the vast majority of patients.

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**AUTHORS' CONTRIBUTION:** Each author contributed individually and significantly to the development of this manuscript. SV and FV were the main contributors to writing this manuscript. FV designed the conception of the modified Salter osteotomy described in this article, performed surgeries, performed the manuscript's final revision, and approved it for submission. SV performed the literature search, followed the patients and collected clinical and radiological results, created the design of this article, performed the statistical analysis, and wrote the draft of this manuscript. SV and FV evaluated clinical and radiological results, discussed the results, and performed data analysis and interpretation.

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# TREATMENT OF THORACOLUMBAR FRACTURES BY CLOSED REDUCTION VIA A PERCUTANEOUS SOLID PEDICLE SCREW

## TRATAMENTO DE FRATURAS TORACOLOMBARES POR REDUÇÃO FECHADA COM PARAFUSO DE PEDÍCULO PERCUTÂNEO

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### ABSTRACT

**Objective:** Investigate the effect of closed reduction and percutaneous pedicle screw fixation in treating thoracolumbar fractures. **Methods:** This retrospective study analyzed 12 cases of single-segment thoracolumbar spine fractures without spinal cord and nerve injury at our department from March 2016 to September 2017. Patients were treated with closed reduction, percutaneous reduction, and internal fixation with solid pedicle screws. The operation time, intraoperative blood loss, anterior vertebral body height ratio (AVHR), Cobb angle (CA) of sagittal kyphosis, and VAS of back pain were determined and statistically compared. **Results:** The average operation time was  $147.2 \pm 45.6$  min, and the average intraoperative bleeding was  $67.8 \pm 34.2$  mL. All fractured vertebrae were completely reduced, their height was restored, and kyphosis was corrected. The average follow-up period was  $10.6 \pm 2.7$  months, with significant improvements seen in the AVHR, CA of sagittal kyphosis, and VAS score ( $P < 0.01$ ). One case had a broken rod after three months, and another had a postoperative infection. All the patients achieved bony healing. **Conclusion:** The treatment of thoracolumbar fractures by closed reduction and internal fixation with a percutaneous solid pedicle screw is simple, effective, and economical. **Level of Evidence VI; Therapeutic Study, Case Series.**

**Keywords:** Closed Fracture Reduction. Spinal Fractures. Pedicle Screws. Fracture Fixation, Internal.

### RESUMO

**Objetivo:** Investigar o efeito da redução incruenta e da fixação com parafuso de pedículo percutâneo no tratamento das fraturas toracolumbares. **Métodos:** Este estudo retrospectivo analisou 12 casos de fraturas toracolumbares com segmento único sem lesão medular ou neural, encontrados no departamento dentro do período de março de 2016 a setembro de 2017. Os pacientes foram tratados com redução fechada e fixação interna com parafusos de pedículo percutâneo. O tempo de operação, a perda sanguínea intra-operatória, a relação da altura do corpo vertebral anterior (AVHR), o ângulo de Cobb (CA) da cifose sagital e a EVA relativa à dor nas costas foram determinados e comparados estatisticamente. **Resultados:** O tempo médio da operação foi de  $147,2 \pm 45,6$  min, com sangramento intraoperatório médio de  $67,8 \pm 34,2$  mL. Todas as vértebras fraturadas foram completamente reduzidas, suas alturas foram restauradas e a cifose foi corrigida. O período médio de acompanhamento foi de  $10,6 \pm 2,7$  meses, apresentando melhorias significativas observadas no AVHR, CA da cifose sagital e pontuação VAS ( $P < 0,01$ ). Um caso teve uma haste quebrada após 3 meses, e outro paciente apresentou uma infecção pós-operatória. Todos os pacientes alcançaram a recuperação óssea. **Conclusão:** O tratamento das fraturas toracolumbares por redução fechada com fixação interna pelo parafuso de pedículo percutâneo é simples, eficaz e econômico. **Nível de Evidência IV; Estudos Terapêuticos, Série de Casos.**

**Descritores:** Redução Fechada. Fraturas da Coluna Vertebral. Parafusos Pediculares. Fixação Interna de Fraturas.

**Citation:** Cheng C, Li G, Luo Y, Lin Zhoudan. Treatment of thoracolumbar fractures by closed reduction via a percutaneous solid pedicle screw. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 4. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Recent developments in minimally invasive technology for spinal surgery include the continuous invention and improvement of minimally invasive surgical instruments. For thoracolumbar fractures without spinal cord and nerve injury, more spine surgeons are starting to use the minimally invasive method of closed reduction and percutaneous pedicle screw and screw rod system reduction and fixation, and its clinical applications

are becoming more extensive as well.<sup>1-3</sup> However, the operation method and instruments used still have shortcomings with regard to positioning, screw placement, and reduction, which to a certain extent affects the procedure and its outcomes. Fortunately, the invention and application of a new solid pedicle screw system was able to remedy this. Since March 2016, our department has used this procedure in some thoracolumbar fractures and has achieved good results.

All authors declare no potential conflict of interest related to this article.

The study was conducted at the 923rd Hospital of People's Liberation Army, Nanning, Guangxi, China.

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Article received on 12/16/2021, approved on 07/05/2022.



## MATERIALS AND METHODS

This was a retrospective study based on medical records from the archives of our Hospital from March 2016 to September 2017 (Table 1). This clinical study was approved by our Hospital Medical Ethical Committee (No 923II-ky-2023-002-01), and informed consent for the surgical procedures and inclusion of data was obtained from all patients. A total of 8 males and 4 females with an average age of 34.8 years (range: 20–58 years) were enrolled in the study. There were 6 cases of L1 fracture, 3 cases of T12 fracture, 2 cases of L2 fracture, and 1 case of L5 fracture, all of which were single-segment fractures, comprised of 6 cases of falling injury, 4 cases of traffic accident injury, and 2 cases of heavy injury. All of them were AO type A fractures, with 5 cases of vertebral canal without space-occupying bone mass, and 7 cases with different degrees of fracture mass protruding into the vertebral canal. The affected volume was less than 1/3, and except in 1 case was more than 1/2. A total of 7 cases were operated within 72 h, 4 cases within 5 days, and 1 case within 9 days. The clinical manifestations of all patients were lumbago and back pain, limited lumbar motion, and no lower extremity sensory, motor, or fecal dysfunction. Before the operation, X-ray, CT, and MRI were performed in all cases. There was no absolute contraindication.

### Treatment method

#### Position reduction

All the patients were placed on a pad thin pillow immediately after admission to the hospital. Analgesics were given, and the thickness of the pillow was gradually increased if this was comfortable for the patient.

After general anesthesia, the injured vertebra and the pedicles of the upper and lower vertebra were

initially positioned via a positioner under G-arm fluoroscopy. After disinfecting and spreading the towel, the needle was inserted about 0.5–1 cm into the lateral projection of the pedicle to locate the positioning needle. If there is any deviation after fluoroscopy, the original needle can be retained. A special positioning regulator (Figure 1) was inserted through the original needle, and another needle was inserted into that positioning regulator in order to make the corresponding adjustment according to the deviation direction of the original needle. The positioning needle was directly adjusted by slowly hammering it into the vertebral body; fluoroscopy was performed during this time to ensure that the positioning needle was located in the pedicle, until the positioning needle was located in the middle of the vertebral body. A 2-cm longitudinal incision was made along the positioning needle, cutting the skin, subcutaneous tissue, and fascia, and performing blunt muscle separation. Then, the soft tissue expander was inserted along the positioning guide



**Figure 1.** Percutaneous solid pedicle screw system: A, solid pedicle screw; B, positioning regulator; C, working channel; D, distractor.

needle, leaving the outer sheath as the channel. Next, the opening of the bone opener was inserted, the bone was drilled, and tapping was performed. Finally, the positioning needle was pulled out, and the appropriate solid pedicle screw was inserted. In general, a single-side pedicle screw was placed in the injured vertebrae, and two pedicle screws were placed in the upper and lower vertebrae. After the screws were placed, a special small pull hook was placed on both sides of the screw to expose the U-shaped groove of the screws. After measurement, a titanium rod of appropriate length was pre-bent and then placed in the U-shaped groove. The operating table was adjusted to raise the head and tail of the bed. A special distractor was placed at the joint of the screw and the titanium rod. The lever principle was used to carry out the operation of vertebral body distraction and reduction. Fluoroscopy was used to confirm whether the reduction of the fracture vertebral body was satisfactory, the height of the vertebral body was restored, and kyphosis was corrected. Later, the nuts were tightened, the incision was closed, and drainage was placed.

#### Postoperative management

After the operation, the sensation and movement of the lower limbs were observed closely. Antibiotics were used to prevent infection. The drainage tube was left for 1–2 days, and it was removed after the drainage fluid was less than 50 mL. On the second day after the operation, the patients could get out of bed with braces, but bed rest was still advised. The brace was fixed for 3–4 months. After the operation, the anteroposterior (AP) and lateral view X-rays were reviewed regularly to observe the fracture healing, vertebral height, and physiological curvature of the spine.

#### Statistical analysis

Data were recorded before and after the operation and at the last follow-up visit. The data included height of the vertebral body, Cobb angle of sagittal kyphosis, and visual analog scale (VAS) score; these were compared via the SPSS10.0 software (SPSS Inc., Chicago, IL) for the t-test, with  $P < 0.01$  considered to be statistically significant.

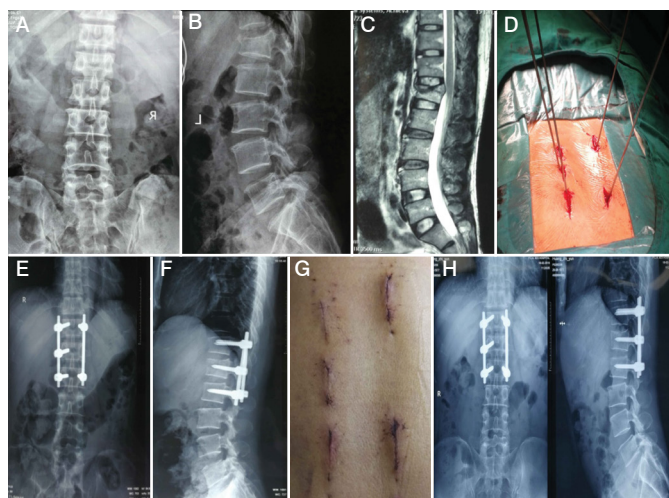
## RESULTS

The operation time lasted an average of  $147.2 \pm 45.6$  min (range: 95–240 min), and the average intraoperative blood loss was  $67.8 \pm 34.2$  mL (range: 20–120 mL). Postoperative follow-up happened after an average of  $10.6 \pm 2.7$  months (range: 6–13 months). All fractured vertebrae were completely reduced, the height of the vertebrae was restored, and kyphosis was corrected. The height of the vertebral body, sagittal kyphotic Cobb angle, and VAS scores, taken before the operation, the second day after the operation, and at the last follow-up, are all shown in Figure 2 and Table 2. All these variables significantly improved after the operation and at the last follow-up ( $P < 0.01$ ). After 3 months, 1 case had a broken rod, but the fracture healed well after follow-up examination, no screw loosening was found, and the patient had

**Table 1.** Patient demographic data.

Demographic data Number
Male gender 8
Female gender 4
Age, years (range) 34.8 (20–58)
Mechanism of injury
Fall from height 6
Road traffic accident 4
Heavy object injury 2
Site of vertebral fracture (%)
T12 3 (25.0)
L1 6 (50.0)
L2 2 (16.7)
L5 1 (8.3)





**Figure 2.** A 32-year-old man with a burst fracture of the lumbar vertebrae. A, B: preoperative X-ray; C: preoperative MRI; D: intraoperative positioning and then inserting the guide needle; E, F: postoperative X-ray; G: postoperative incision; H: review of X-ray after 1 year of operation.

**Table 2.** Perioperative anterior vertebral body height ratio (VBH), Cobb angle of sagittal kyphosis (CA), and visual analog scale (VAS) ( $\bar{x} \pm s$ ,  $n = 12$ ).

	VBH	CA	VAS
Preoperative	$72.4 \pm 9.4$	$14.4 \pm 6.7$	$6.6 \pm 0.9$
Postoperative	$99.5 \pm 8.1$	$6.5 \pm 4.3$	$1.9 \pm 0.6$
Last follow-up	$97.6 \pm 8.4$	$6.9 \pm 4.3$	$0.8 \pm 0.7$

\*Compared with postoperative, final follow-up,  $P < 0.01$ .

no uncomfortable symptoms. Another patient had postoperative infection, but after antibiotic treatment, symptoms improved and the patient was discharged from the hospital. Half a year later, the upper vertebra space collapsed, but this recovered to normal after a reoperation.

## DISCUSSION

Most thoracolumbar fractures can yield good results through conservative treatment. With the invention and application of pedicle screws, surgical treatment has become an important means of thoracolumbar fracture treatment. It can restore the height of the vertebral body, correct kyphosis, immediately relieve symptoms, and get patients out of bed as soon as possible, greatly reducing the incidence of bed complications.

With the advancements of minimally invasive surgery, percutaneous pedicle screw placement technology has developed rapidly as well, which can improve the current surgical treatment for thoracolumbar fractures.<sup>4-6</sup> Percutaneous pedicle screw insertion technology is usually operated step-by-step under the fluoroscope of a C-arm or G-arm with the help of special surgical instruments. Currently, the most commonly used percutaneous pedicle internal fixation systems are the Viper system from DePuy, the sextant system from Medtronic, the Matis system from Stryke, and the upass system from the domestic company Weigao; these are all hollow pedicle screw systems. The minimally invasive treatment of vertebral fractures has achieved good results and is already being widely used.<sup>7,8</sup> However, there are still some weaknesses in the hollow pedicle system. First, there is no advantage in the positioning process. Although there is C-arm or G-arm fluoroscopy, it is not easy to find the ideal screw entry point accurately in the closed state, which is completely based on the experience and hand feeling of the operator. Second,

most of the hollow screws are multiaxial screws, and the strength of their vertebral body reduction is not enough. Third, the design of reduction equipment is unreasonable and does not yield good results in terms of vertebral body reduction.

The key to reducing vertebral fractures lies in the reduction ability and maintenance ability of the screws. Arbash et al.<sup>9</sup> found that, although there is no statistical difference between solid and hollow screws in maintaining the correction of kyphosis and vertebral height, the former has stronger correction ability. The reduction devices and techniques also play an important role. The improvement of several reduction devices and the reasonable application of reduction techniques have achieved satisfactory reduction results.<sup>10-13</sup> In light of the previously mentioned problems, He Xinning<sup>14</sup> designed a percutaneous solid pedicle screw system. This system uses a short tail solid uniaxial pedicle screw, with a sophisticated positioning needle regulator and distraction reduction forceps, so that the whole operation process is easier and more programmed, and the effect is better. It has three advantages. First, as long as the first puncture of the positioning needle is not too biased, most of them can be corrected by inserting the positioning needle into its regulator and then inserting another positioning needle according to the direction of deviation; this saves time from the traditional method of positioning with a fluoroscope. Second, the solid uniaxial pedicle screw has the same effect as a conventional open screw in its fixation and distraction functions, making it better than the hollow multiaxial screw. Third, the design of the distraction reduction forceps makes full use of the mechanical principle of the lever and combines it with the position reduction before and during the operation; thus, reduction of the vertebral body becomes very easy.

In our study, the percutaneous solid pedicle screw system was used for minimally invasive surgery, and the whole process of positioning and puncture was relatively smooth. Compared with the previous hollow screw fixation system, the positioning time was greatly shortened, and the number of fluoroscopy was significantly reduced, which was greatly beneficial for patients and doctors. Although it is a solid screw, the process of pedicle screw placement is not different from that of a hollow screw. Depending on the preparation of a good working channel, screw placement is generally easy. The greatest advantage of this set of solid screws lies in its strong ability to reduce vertebral fracture. The unique fixation characteristics of uniaxial screws, which have more strength to open and reduce the vertebral fractures, make up for the disadvantages of multiaxial screws with uncertain direction. In combination with the role of body position reduction and distractor, most of the fractured vertebral bodies were completely reduced, and the height of the vertebral body was restored, kyphosis was corrected, and the bone blocks protruding into the vertebral canal were restored. No case needed open reduction or decompression.

The study showed that, except for a few cases with a long operation time in the early stage, the operation time in the later stage was significantly shortened due to the improvement of the proficiency of instrument operation. Generally, the operation can be completed in over an hour, and the amount of blood loss in the operation was very small, with an average of about 40 mL. The postoperative pain was significantly improved, and the VAS score significantly improved after the operation and the last follow-up. The height of the vertebral body generally recovered after the operation. Although some cases lost height at different degrees at the last follow-up, this had no significant difference compared with the postoperative data. The Cobb angle of sagittal kyphosis decreased after the operation, and this was slightly lost in some cases at the last follow-up, but this was not significantly different compared with the postoperative data. We also analyzed reasons for the loss of the height of the vertebral

body and Cobb angle of the sagittal kyphosis of the spine during the last follow-up. Two main factors are considered. The first is being allowed to leave bed too early. Although the fractured vertebral body can be reduced by surgery, it is difficult for the cancellous bone to reexpand, leaving a gap in the vertebral body. If the patients start to walk without complete bone healing, it may be difficult to maintain the dimension only through the support of the screws, so the height of the vertebral body is lost and it is easy to break the screw and the rod. In our group, there was a broken rod. Although the final fracture healing was good, it also increased the risk of fracture healing and reduced the quality of fracture healing. The second factor is that there is no bone graft in the vertebral body and the space in the vertebral body is not filled, affecting the speed of fracture healing, thus leading to the collapse of the vertebral body after getting out of bed. On the basis of the above, there are two areas of improvement. The first is to carry out intravertebral bone grafting and transpedicular allogeneic bone grafting. The second is to either appropriately delay the time of getting out of bed or impose restrictions when doing so. This can be carried out by wearing supportive protection and strictly controlling the time spent outside of bed. A number of studies have confirmed that percutaneous pedicle screw reduction and fixation at

the fractured vertebra for thoracolumbar fractures is associated with better recovery and a maintained height of the injured vertebra.<sup>15,16</sup> In the later cases of our group, the method of fixation and reduction of the injured vertebra by a percutaneous pedicle screw at the fractured vertebra was used routinely with positive outcomes.

Although the percutaneous solid pedicle screw system has obvious advantages for the reduction of thoracolumbar fractures, there are still some problems in the system that need further improvement. For example, the screw can be designed as a long tail nail to make titanium rod implantation and other operations easier. Some improvements of the distractor also need to be made in order to make the procedure easier.

## CONCLUSIONS

In this preliminary retrospective study of 12 patients, we have shown that closed reduction and percutaneous internal fixation using a solid pedicle screw system in the treatment of thoracolumbar fractures could effectively restore and maintain vertebral height. This is a relatively simple, acceptable, low-cost, and minimally invasive surgical choice for patients with type A thoracolumbar fractures.

**AUTHORS' CONTRIBUTION:** CC supervised the entire project and wrote the manuscript with comments from all coauthors. CC and GL participated in the study design. CC, GL, YL and ZL processed the data collection and analysis. All authors read and approved the final manuscript. We have no potential conflict of interest and copyright constraints.

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# HARVESTING SURAL FLAP WITH COVERED PEDICLE

## COLETA DE RETALHO SURAL COM PEDÍCULO COBERTO

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### ABSTRACT

**Objective:** The aim was to evaluate the viability and the outcomes of the sural flap performed with the pedicle covered by a strip of skin. **Methods:** A prospective cohort of 20 consecutive cases were evaluated in terms of flap viability, complication rate, and the amount of skin graft required. The location of the defects was the middle third of the tibia in 3 cases, the ankle and hindfoot in 15 cases, the middle foot in 1 case, and the forefoot in 1 case. The flap design was the same as described by Masquelet. The only modification included a strip of skin over the entire length of the pedicle. The intermediary skin between the donor site and the defect was incised and the skin was undermined to accommodate the pedicle without compression. **Results:** All cases had a satisfactory evolution, with adequate healing and without flap loss. Both the donor site and the pedicle were primarily closed in all cases. In one patient, the flap developed a limited area of superficial epidermolysis that healed spontaneously. **Conclusion:** the modified sural flap with a covered pedicle is feasible and reliable with a lower rate of complications when compared with the conventional sural flap. **Level of Evidence IV, Cohort Studies.**

**Keywords:** Tissue Transplantation, Surgical Flaps, Free Tissue Flaps.

### RESUMO

**Objetivo:** O objetivo foi avaliar a viabilidade e os resultados do retalho sural realizado com o pedículo coberto com uma faixa de pele. **Material e Métodos:** Pelo estudo de coorte prospectivo, foram avaliados 20 casos consecutivos considerando a viabilidade do retalho, a taxa de complicações e a quantidade de enxerto de pele necessária. A localização dos defeitos foi no terço médio da tibia em 3 casos, tornozelo e retopé em 15 casos, pé médio em 1 caso e antepé em 1 caso. O desenho do retalho foi o mesmo que o descrito por Masquelet. A única modificação foi a inclusão de uma tira de pele em todo o comprimento do pedículo. A pele intermediária entre o local doador e o defeito foi incisada e a pele foi descolada para acomodar o pedículo sem compressão. **Resultados:** Todos os casos tiveram uma evolução satisfatória, com cicatrização adequada e sem perda dos retalhos. Tanto o local doador quanto o pedículo foram primariamente fechados em todos os casos. Em um paciente, o retalho desenvolveu uma área limitada de epidermólise superficial que cicatrizou espontaneamente. **Conclusão:** O retalho sural modificado com pedículo coberto é viável e confiável com uma menor taxa de complicações quando comparado ao retalho sural convencional. **Nível de Evidência IV, Estudos de Coorte.**

**Descritores:** Transplante de Tecidos, Retalhos Cirúrgicos, Retalhos de Tecido Biológico.

**Citation:** Cho AB, Ferreira CHV, Mendonça PGM, Sorrenti L, Kiyohara LY. Harvesting sural flap with covered pedicle. Acta Ortop Bras. [online]. 2023;31(1) Esp.: Page 1 of 3. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

The traditional sural flap as described by Masquelet<sup>1</sup> is based on the suprafascial course of the sural nerve and includes the lesser saphenous vein for venous return. The pedicle is dissected down to the distal leg until the classic pivot point, about 5 cm above the lateral malleolus<sup>1,2</sup>. It can suffer torsion or compression during transposition of the flap to the recipient area<sup>1-5</sup>. To minimize the risk of pedicle compression, the flap should not be transposed through a subcutaneous tunnel because the skin surrounding the defect might act as a constricting sling due to fibrosis and local edema, jeopardising the venous return. This is often reported as a major cause of flap congestion, resulting in partial or complete flap loss<sup>3</sup>.

The aim of this study is to evaluate the viability and the outcomes of the sural flap performed with a technical modification, in which the pedicle is covered by a strip of skin, avoiding tunnelization of the pedicle.

### PATIENT AND METHODS

Between march 2018 and September 2020, 20 consecutive cases of reverse sural flaps were performed in 20 patients (Table 1). Seventeen were male and three was female. The cause of the soft tissue defect was post-traumatic crushing injuries in 15 cases. The average time from the trauma and the soft-tissue coverage with the sural flap was 1 week. In the other five cases, one was performed

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Hospital Estadual Mário Covas, Santo André, SP, Brazil.

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Article received on 10/31/2021, approved in 02/08/2022.



**Table 1.** Patients demographics. Wound location and ethology, flap's and pedicle's length and width and complications.

Patient	Age (year)	Gender	Location of the defect	Etiology	Flap size (length x width) cm	Skin strip size (width x length) cm	Outcomes (Months)	Complications
1	25	Male	Medial Malleolus	Tumor	13 x 5	1,5 x 13	30	None
2	32	Male	Distal Tiibia	Traumatic (motorcycle Accident)	10,0 x 4,0	1,5 x 8	28	None
3	30	Female	Medial Malleolus	Traumatic (Car Accident)	6,0 x 4,5	3 x 10,5	28	None
4	63	Female	AquillesTendon	Post-Op	6,0 x 3,0	1,5 x 7,5	26	None
5	35	Male	Distal Tiibia	Traumatic (motorcycle Accident)	13,0 x 3,5	1 x 8	24	None
6	42	Male	Distal Tibia	Traumatic (motorcycle Accident)	12,0 x 3,0	1,5 x 8	24	None
7	36	Male	Tibial Shaft	Traumatic (motorcycle Accident)	7,5 x 4,3	2,5x 13,0	24	None
8	41	Male	MindFoot	Traumatic (motorcycle Accident)	11,0 x 6,0	2,5 x 14	22	None
9	18	Male	Tibial Shaft	Osteomyelitis chronic	13,5 x 4,5	1,5 x 13	18	None
10	32	Male	Medial Malleolus	Traumatic (motorcycle Accident)	14,0 x 6,5	1,5 x 7	13	None
11	35	Male	Lateral Malleolus	Traumatic (motorcycle Accident)	10 x 5	2 x 14	12	Pedicle Epidermolysis
12	25	Male	ForeFoot	Traumatic (motorcycle Accident)	13,0 x 5,0	1 x 10	11	None
13	30	Male	HindFoot	Chopart Traumatic Amputation	14,5 x 6,5	1,5 x 13,5	11	None
14	60	Male	HindFoot	Post-Op Calcaneus Fracture	4 x 3,0	1,0 x 6,0	7	None
15	8	Male	Tibial Shaft	Traumatic (Running Over)	7,0 x 4,5	1,5 x 5,0	6	None
16	55	Female	AquillesTendon	Post-OP	5,0 x 3,0	2,0 x 5,0	6	None
17	32	Male	Medial Malleolus	Traumatic (motorcycle Accident)	9,0 x 4,0	1,5 x 5,0	5	None
18	25	Male	Medial Malleolus	Traumatic (Running Over)	15,0 x 9,0	2,0 x 10,0	2	None
19	30	Male	Lateral Malleolus	Traumatic (motorcycle Accident)	14,0 x 6,0	2,0 x 9,0	2	None
20	8	Male	Lateral Malleolus	Traumatic (Running Over)	7,0 x 4,5	1,5 x 5,0	1	None

for tumor lesion, one was performed for chronic osteomyelitis and the other two for wound dehiscence, one after achilles tendon repair and one after calcaneus osteosynthesis. The location of the defects was the middle third of the tibia in 3 cases, ankle and hindfoot in 15 cases, middle foot in 1 case and forefoot in 1 case. All flaps were performed by three different surgeons in the same University Hospital. The mean age of the patients was 33,1, ranging from 8 to 63 years old. The minimum follow-up required for inclusion in this study was 1 month.

### Surgical Technique

The main aspect of this technical modification was the extension of the flap's skin island over the entire length of the pedicle, as a longitudinal strip of skin in continuity with the flap itself, like a "squash racket" (Figure 1). The width of this strip of skin was planned to cover both the sural nerve and the lesser saphenous vein, including the vascular network between them (Figure 2). The flap dissection was performed in standard fashion, from proximal to distal, with care to maintain the connection between the strip of skin and the neurovascular pedicle and its connective tissue. After the complete dissection of the flap and its covered pedicle, the flap's transposition was simulated over the intact skin between the recipient and donor sites. The intact skin was then incised over the predicted course and the flap inset was performed (Figure 3). The strip of skin over the pedicle was sutured to the undermined skin between the recipient and donor sites without any tension (Figure 4).

### RESULTS

The average width of the flaps was 4,74 cm, ranging from 9,0 to 3,0 cm, while the average length was 10,22 cm, ranging from 15,0 to 6,0 cm. The average width of the skin strip over the pedicle was 1,61 cm, ranging from 3,0 to 1,0 cm, while the average length was 9,22 cm, ranging from 14 to 5 cm. The donor site of the flaps were primarily closed in all cases. The average follow up was 15 months, ranging 1 to 30 months.



**Figure 1.** Flap's design. Longitudinal strip of skin in continuity with the flap itself resembling a squash racket.

All flaps survived without any major complication or surgical re-intervention. Only one patient presented a minor superficial epidermolysis within the strip of skin over the pedicle, resolved without the need for any debridement or surgical intervention. No skin graft was required to cover the pedicle or donor site of the sural flap in all cases.

The survival rate of the flaps were 100% (20/20). There was no case of total or partial flap loss. The unique case of minor epidermolysis at the pedicle was very limited (1,0 x 0,5 cm) and superficial and resolved spontaneously.

### DISCUSSION

Although very popular and reliable, the traditional sural flap has some shortcomings. The main reported complication is venous congestion resulting in partial or complete flap loss 3,6-8. Therefore, many authors advise against tunnelization of the pedicle during the flap



**Figure 2.** The strip of skin was planned to cover both the sural nerve and the lesser saphenous vein.



**Figure 3.** The intact skin between the recipient and donor sites was incised to allow the accommodation of the pedicle.

transposition. Instead, they propose a connecting incision between the flap's rotation point and the recipient wound to accommodate the pedicle. In this scenario, variable amounts of skin graft are required to cover the pedicle, since the connecting incision cannot be primarily closed over the pedicle due to the risk of compression.



**Figure 4.** The strip of skin over the pedicle was sutured to the undermined skin between the recipient and donor sites without any tension. The donor site was also primarily closed.

In 2009, Vendramin<sup>3</sup> described a technical modification in the sural flap with the inclusion of a strip of skin to cover the flap's pedicle. He observed that the complication rate was reduced from 22.2% to 8.8%.

This study was a prospective cohort of 20 consecutive cases of reverse rural flap using the same technical modification as described by Vendramin and Lee et al 3,9. There was no necessity of tunnelization of the pedicle, since the strip of skin over the pedicle allowed a direct closure of the connecting incision with a tension-free accommodation of the neurovascular bundle. In addition, all patients in this study underwent primary closure of the donor area, requiring no skin graft to cover the vascular pedicle.

There was no flap loss in this study, either complete or partial. The unique case of minor epidermolysis at the pedicle was very limited and superficial. No surgical procedure for flap complication was necessary. If we consider this mild epidermolysis as a complication, we end up with a complication rate of approximately 5%, which is quite lower than previous studies 1,3,6,7. We hypothesize that this strip of skin over the pedicle might be acted as a facilitator for venous drainage as well.

We conclude that this modified sural flap with covered pedicle is feasible and reliable, with a lower rate of complications when compared with the conventional sural flap.

**AUTHORS' CONTRIBUTION:** Each author contributed individually and significantly to the development of this article. ABC: Review of the article, performing surgeries and intellectual concept of the article; CHVF: Writing, performing surgeries, data analysis, reviewing the article and intellectual concept; PGMM: writing the article and analyzing the data; LS: article review, data analysis; LYK: article review, data analysis

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# COMBINED PLATE VERSUS EXTERNAL FIXATION FOR DISTAL RADIUS FRACTURES

## PLACA COMBINADA VERSUS FIXAÇÃO EXTERNA PARA FRATURAS DO RÁDIO DISTAL

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### ABSTRACT

**Objective:** This study aimed to compare the functional and radiological results of patients who had intra-articular comminuted distal radius fractures and were operated on with external fixation percutaneous pinning or the volar-dorsal combined plate osteosynthesis. **Methods:** In this study, 49 patients operated on and followed up for the comminuted distal radius fractures between May 2015 and January 2019 were retrospectively evaluated. The surgical outcomes of the patients, who were operated on with combined dorsal-volar plate osteosynthesis or external fixation percutaneous pinning, were compared in this study. Functional and radiological scores were evaluated and analyzed statistically. **Results:** There was no statistical difference between external fixation and volar-dorsal combined plate groups regarding the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, the Visual Analog Scale (VAS), the Mayo scoring system, range of motion, and grip strength values. **Discussion:** Although the combined volar-dorsal plate osteosynthesis technique had a longer operation time and a more complicated surgical procedure, the combined volar-dorsal plate osteosynthesis had lower complication rates and permitted early mobilization. The combined volar-dorsal plate osteosynthesis could be an alternative to external fixation percutaneous pinning. **Level of Evidence III, Therapeutic Studies Investigating the Results of Treatment.**

**Keywords:** Fractures, Bone, Radius Fractures, Fracture Fixation, Bone Plates.

### RESUMO

**Objetivo:** O objetivo deste estudo foi comparar os resultados funcionais e radiológicos de pacientes portadores de fraturas intra-articulares cominutivas do rádio distal, operados com fixação externa percutânea ou com osteossíntese volar-dorsal de placa combinada. **Método:** Foram avaliados 49 pacientes operados e acompanhados por fraturas cominutivas distais do rádio entre maio de 2015 e janeiro de 2019 retrospectivamente. Os resultados cirúrgicos dos pacientes operados com osteossíntese de placa volar-dorsal combinada ou fixação externa percutânea foram comparados. Os escores funcionais e radiológicos foram avaliados e analisados estatisticamente. **Resultados:** Não houve diferença estatística entre os grupos de fixação externa e placa combinada volar-dorsal em relação ao questionário Deficiências do braço, ombro e mão (DASH), à Escala Visual Analógica (VAS), ao sistema de pontuação Mayo, à amplitude de movimento ou à avaliação de força de preensão. **Conclusão:** Embora a técnica combinada de osteossíntese da placa volar-dorsal tenha um tempo cirúrgico mais longo e procedimento mais complicado, a osteossíntese combinada da placa volar-dorsal apresentou menores taxas de complicações, permitindo a mobilização precoce. A osteossíntese combinada da placa volar-dorsal pode ser uma alternativa à fixação externa percutânea. **Nível de Evidência III, Estudos terapêuticos – Investigação dos resultados do tratamento.**

**Descritores:** Fraturas Ósseas, Fraturas do Rádio, Fixação de Fratura, Placas Ósseas.

**Citation:** Polat O, Toy S, Özbay H. Combined plate versus external fixation for distal radius fractures. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 5. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Distal radius fractures are among the most common fracture.<sup>1</sup> Distal radius fractures account for 7.5% of all fractures and 15.7% of all upper extremity fractures.<sup>2</sup> The functional outcome of distal radius fractures is affected by extra-articular alignment, anatomical reduction of the articular surface, intra-articular soft tissue injuries, and postoperative complications.<sup>3-5</sup>

Although the traditional treatment is direct reduction plastering, surgery is required for intra-articular and unstable fractures. Many surgical procedures are available. These are percutaneous pinning, external fixation, volar plating, and dorsal plating.<sup>6-8</sup> Percutaneous pinning is mostly used for extra-articular fractures.<sup>9-11</sup> The volar plating technique is preferred by most surgeons because of its relatively easy surgical approach, facilitating early motion

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Ağrı Training and Research Hospital, Department of Orthopedics and Traumatology, Ağrı, Turkey.

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Article received on 06/03/2021, approved in 05/04/2022.



initiation, and having fewer soft tissue complications than dorsal plating.<sup>7</sup> However, it is challenging to fix dorsal parts with volar plates. Dorsal plates are used to fix dorsal parts, but the surgeon avoids dorsal plates due to the high incidence of complications such as extensor tendon irritation and rupture. In addition, the adaptation of the plate to the radius anatomy is difficult.<sup>12</sup>

External fixation neutralizes the pressure forces in the fracture area by applying distraction to the joint surface. External fixation is supported by percutaneous or mini-open methods. External fixation has been described as a treatment modality equally suitable for volar plating in dorsally displaced intra-articular distal radius fractures.<sup>8-13</sup> Partial intra-articular fracture treatments may not be sufficient. Intra-articular fractures are displaced in more than one plane. Intra-articular comminuted fractures are mostly treated with percutaneous pinning complementary to external fixation.<sup>14</sup> The disadvantage of this method is that the joint surface cannot be corrected sufficiently due to the fact that arthrotomy cannot be performed during the surgery, and the joint range of motion cannot be achieved due to the inability to give early motion.<sup>3-6</sup>

In this study, we aimed to compare the functional and radiological results of patients, who had intra-articular comminuted distal radius fractures, were operated on with external fixation percutaneous pinning or combined volar-dorsal plate. We, in this study, hypothesized that the dorsal-volar combined plate osteosynthesis might be superior to the external fixation percutaneous pinning for distal radius comminuted fractures in terms of clinical functionality.

## METHODS

### Design and Sample

In this study, patients who were operated on and followed up for the comminuted distal radius fractures between May 2015 and January 2019 were retrospectively evaluated. The study protocol was approved by the local ethics committee (IRB Date/No:28.01.2021/35). Written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The inclusion criteria were as follows: (1) patients were operated on with the combined dorsal-volar plating and external fixation to treat complex four-part distal radius fractures (shaft, radial styloid process, dorsal medial facet, and volar medial facet) between May 2015 and January 2019; (2) patients with at least two years of follow-up and regular follow-up. The exclusion criteria were as follows: (1) patients whose bone maturation was incomplete ( $n=2$ ); (2) patients with additional injuries in the same extremity ( $n=3$ ); (3) fractures extending into diaphysis ( $n=3$ ); open and pathological fractures ( $n=2$ ); (4) patients had previously undergone surgery on the same extremity ( $n=3$ ). Five patients were excluded during the follow-up. Forty-nine patients (20 females, 29 males; mean age  $43.85 \pm 15.78$ ; range, 18 to 74 years) who met the criteria were included.

The patients were divided into two groups. Combined volar-dorsal plates (Group 1) were applied to 23 patients (46.9%). Twenty-six patients (53.1%) were operated on with external fixation (Group 2). The operation method was made according to the surgeon's own experience and preference. One surgeon applied the combined volar-dorsal plate for complex fractures, while another surgeon performed the external fixation.

### Surgical Procedures

Two orthopedic surgeons performed all surgical procedures. Closed reduction was performed for external fixation using image intensification. Percutaneous K-wires or small elevators through a small incision for manipulation were used when complete reduction after closed reduction could not be achieved (Figure 1). Arthrotomy



**Figure 1.** A) Preoperative anteroposterior radiograph showing distal radius fracture, distal radius fracture, AO 2R3-C3, Melone type 4. B) Preoperative lateral radiograph showing distal radius fracture, distal radius fracture, AO 2R3-C3, Melone type 4. C) Early postoperatively X-ray with anteroposterior after fixation with an external fixator. D) Early postoperatively X-ray with lateral after fixation with an external fixator. E) X-ray with anteroposterior after the implant removal. F) X-ray with lateral after the implant removal.

was not performed for any patients. K-wires were typically 1.6 mm in size. One uniplanar bridging external fixator (TST, Istanbul, Turkey) system was used. External fixations were removed in the outpatient clinic at 4 to 6 weeks. Then, all patients were given standardized physical therapy for two weeks. Then, home exercises were instructed five times a day.

For combined volar-dorsal plate fixation, a volar anatomically locked distal radius plate was placed using the standard volar Henry approach. The insertion of brachioradialis was loosened for radius styloid reduction and to ensure radial inclination. Volar facet fixation was used as a template for other fragments. Then the second incision over Lister's tubercle was used. The extensor retinaculum was opened in the S-shape. Tendons and posterior interosseous nerve were mobilized, and dorsal capsulotomy was performed. Articular fragments were reduced and supported with allograft if needed. Lunate facet and styloid process were fixed with locked 2 mm miniplates. After dorsal plate fixation, the extensor retinaculum tendon was used to cover the dorsal plate. Then, screws of the volar plate for the radial styloid were inserted. Ulnar styloid fractures were not fixed. (Figure 2) Fluoroscopic imaging was used for the assessment of articular reduction. Active and passive wrist and finger motions were started on the postoperative first day. After three weeks, physical therapy was initiated.

### Outcome Measures

Arbeitsgemeinschaft für Osteosynthesefragen (AO)/Orthopaedic Trauma Association (OTA) and Melone classifications were used for classification of distal radius fractures. All fractures were evaluated with X-ray imaging.

Follow-ups were in one week, three weeks and six weeks, three months, six months, 12 months, and 24 months. Mayo wrist score, DASH (The Disabilities of the Arm, Shoulder, and Hand) questionnaire, and VAS (the Visual Analog Scale) were evaluated for scoring systems. Clinically, the grip strength of the operated side and the





**Figure 2.** A) Preoperative anteroposterior radiograph showing distal radius fracture, AO 2R3-C3, Melone type 2a. B) Preoperative lateral radiograph showing distal radius fracture, AO 2R3-C3, Melone type 2a. C) X-ray with anteroposterior after fixation with the combined volar-dorsal plates. D) X-ray with lateral after fixation with the combined volar-dorsal plates.

opposite side were evaluated. Radiologically, radioulnar deviation arc (radial deviation plus ulnar deviation degree), volar tilt, radial inclination, radial height, ulnar variance, and carpal sag (translation of the carpus with respect to the long axis of the radius) were evaluated.<sup>15-17</sup>

### Statistical Analysis

Statistical analysis was performed using the IBM SPSS for Windows version 25.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean  $\pm$  standard deviation (SD), range (min-max), or number and frequency, where applicable. The Kolmogorov-Smirnov test was used to determine whether the data were distributed normally. Independent samples t-test was used to compare the groups. Paired samples t-test was used to compare the data within the group. A p-value of  $p < 0.05$  was considered statistically significant.

### RESULTS

According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO)/Orthopaedic Trauma Association (OTA) classification, all fractures were 2R3-C3. According to Melone classification, 11 fractures were type 2a (22.4%), 13 were type 2b (26.5%), seven were type 3 (14.3%), and 18 were type 4 (36.7%).<sup>18</sup> (Table 1) Gender, side, and dominance were shown in Table 1.

Combined volar-dorsal plates were applied to 23 patients (46.9%) out of 49 patients, and 26 patients (53.1%) were operated on with external fixation. The mean interval between injury and surgery was  $4.52 \pm 2.12$  (range: 1 to 9) days in the combined volar-dorsal plate group and  $3.38 \pm 1.76$  (range: 1-7) days in the external fixation group. There was a statistical difference between two groups ( $p=0.047$ ). The mean duration of hospitalization was  $5.34 \pm 2.28$  (range: 3 to 12) days in the combined volar-dorsal plate group and  $2.84 \pm 0.88$  (range: 2 to 4) days in the external fixation group. There was a

statistical difference between two groups ( $p<0.001$ ). The mean follow-up time was  $3.17 \pm 1.07$  (range: 2-5) years in the combined volar-dorsal plate group and  $3.76 \pm 1.5$  (range: 2-6) years in the external fixation group. There was no statistical difference between two groups ( $p=0.155$ ). (Table 2)

The mean operation time was  $103.04 \pm 12.76$  (range: 85 to 130) minutes in the combined volar-dorsal plate group and  $53.46 \pm 11.02$  (range: 40-75) minutes in the external fixation group. There was a statistical difference between two groups ( $p<0.001$ ). The mean radio-ulnar deviation arc was  $41.17^\circ \pm 7.13^\circ$  (range:  $28^\circ$  to  $58^\circ$ )

**Table 1.** Comparison of the demographical characteristics and Mayo scores between groups.

		Group 1 n: 23		Group 2 n: 26		TOTAL n: 49		p-value
		n	%	n	%	n	%	
Gender	Female	8	34.8	12	46.2	20	40.8	0.430
	Male	15	65.2	14	53.8	29	59.2	
Side	Right	16	69.6	18	69.2	34	69.4	0.980
	Left	7	30.4	8	30.8	15	30.6	
Melone Classification	Type 2a	9	39.1	2	7.7	11	22.4	0.030*
	Type 2b	5	21.7	8	30.8	13	26.5	
	Type 3	3	13.0	4	15.4	7	14.3	
	Type 4	6	26.1	12	46.2	18	36.7	
Dominance	Dominant side	15	65.2	20	76.9	35	71.4	0.376
	Nondominant side	8	34.8	6	23.1	14	28.6	
Injury Mechanism	Motor vehicle accident	2	8.7	6	23.1	8	16.3	0.006*
	Falling	12	52.2	18	69.2	30	61.2	
	Work accident	5	21.7	2	7.7	7	14.3	
	Sports injury	4	17.4	0	0	4	8.2	
MAYO	Poor	3	13.0	6	23.1	9	18.4	0.391
	Good	7	30.4	10	38.5	17	34.7	
	Satisfactory	6	26.1	2	7.7	8	16.3	
	Excellent	7	30.4	8	30.8	15	30.6	

\* Independent samples t-test.

**Table 2.** Functional and radiological results of patients.

	Group 1 n: 23	Group 2 n: 26	TOTAL n: 49	p-value
	Mean (SD)	Mean (SD)	Mean (SD)	
Age	44.00 (12.47)	43.73 (18.48)	43.85 (15.78)	0.952
Time between trauma and surgery (day)	4.52 (2.12)	3.38 (1.76)	3.91 (2.00)	0.047*
Hospitalization time (day)	5.34 (2.28)	2.84 (0.88)	4.02 (2.09)	<0.001*
Operation time (minutes)	103.04 (12.76)	53.46 (11.02)	76.73 (27.62)	<0.001*
Follow-up time (year)	3.17 (1.07)	3.76 (1.50)	3.49 (1.34)	0.115
DASH	10.87 (8.12)	14.92 (9.10)	13.02 (8.81)	0.109
VAS	2.13 (0.96)	2.61 (1.47)	2.38 (1.27)	0.176
Radioulnar deviation arc	41.17 (7.13)	33.46 (9.59)	37.08 (9.29)	0.003*
Flexion angle (degree)	50.00 (14.84)	42.69 (13.80)	46.12 (14.62)	0.081
Extension angle (degree)	53.04 (15.28)	45.38 (13.33)	48.98 (14.64)	0.067
Volar tilt (degree)	8.73 (4.83)	4.15 (9.49)	6.30 (7.94)	0.042*
Radial Inclination (degree)	22.04 (5.18)	18.00 (4.66)	19.89 (5.27)	0.006*
Radial Height (mm)	11.56 (3.5)	12.00 (3.51)	11.79 (3.47)	0.667
Ulnar Variance	1.04 (1.42)	1.00 (1.20)	1.02 (1.29)	0.908
Carpal Sag (mm)	1.07 (0.54)	1.4 (0.55)	1.24 (0.56)	0.047*
Supination-pronation (degree)	147.39 (11.16)	145.92 (11.21)	146.61 (11.10)	0.649

SD: standard deviation. \* Independent Samples t-test.

in combined volar-dorsal plate group and  $33.46^{\circ} \pm 9.59^{\circ}$  (range:  $20^{\circ}$  to  $50^{\circ}$ ) in the external fixation group. There was a statistical difference between two groups ( $p=0.003$ ). (Table 2)

The mean volar tilt was  $8.73^{\circ} \pm 4.83^{\circ}$  (range:  $1^{\circ}$  to  $16^{\circ}$ ) in combined volar-dorsal plate group and  $4.15^{\circ} \pm 9.49^{\circ}$  (range:  $-20^{\circ}$  to  $17^{\circ}$ ) in the external fixation group. There was a statistical difference between two groups ( $p=0.042$ ). The mean radial inclination was  $22.04^{\circ} \pm 5.18^{\circ}$  (range:  $11^{\circ}$  to  $30^{\circ}$ ) in combined volar-dorsal plate group and  $18.00^{\circ} \pm 4.66^{\circ}$  (range:  $9^{\circ}$  to  $26^{\circ}$ ) in the external fixation group. There was a statistical difference between two groups ( $p=0.006$ ). The mean carpal sag was  $1.07 \pm 0.54$  (range: 0.3 to 2) mm in the combined volar-dorsal plate group and  $1.40 \pm 0.55$  (range: 0.2 to 2.4) mm in the external fixation group. There was a statistical difference between two groups ( $p=0.047$ ). (Table 2)

The mean grip strength was  $27.87 \pm 8.84$  (range: 17 to 42) kg and 80% of the opposite side in the combined volar-dorsal plate group. The mean grip strength was  $30.84 \pm 11.07$  (range: 16-47) kg and 87.9% of the opposite side in the external fixation group. There was no statistical difference between two groups ( $p=0.302$ ). (Table 3)

There was no implant irritation, infection, major nerve damage, malunion, non-union, and tendon rupture in combined volar-dorsal plate group. There was complex regional pain syndrome in only three patients. Postoperative swelling and bullous lesions were observed in six patients, which were healed with local wound healing. There was complex regional pain syndrome in six patients in the external fixation group, pin site infection in seven patients, and finger stiffness in three patients. There was no carpal tunnel syndrome, major nerve damage, malunion, non-union, and tendon rupture in external fixation group. A secondary operation was not needed in any patients.

## DISCUSSION

Joint anatomy and design have gained importance recently. Post-traumatic arthrosis development due to joint stepping and advances in plate technologies have increased the importance of open reduction internal fixation.<sup>19</sup> External fixation is a well-proven common treatment for intra-articular distal radius fractures. The reduction is provided by the ligamentotaxis method and supported by percutaneous or mini-open procedures. Limited information is available in the literature regarding the combined dorsal-volar plate.<sup>6-8</sup>

Ring et al. [20] evaluated the results of 25 patients operated on with volar - dorsal plates. They stated that all the fractures were healing. The mean ROM was 56 degrees, and they achieved  $54^{\circ}$  extension,  $51^{\circ}$  flexion,  $79^{\circ}$  pronation, and  $74^{\circ}$  supination. The average grip strength was 78% compared to the opposite side. The mean dorsal angulation of the radius was 2 degrees. They obtained a mean radial tilt of  $21^{\circ}$ , 0.8 mm positive ulnar variance, and 0.7 mm joint displacement. Seven patients developed radiographic signs of arthrosis. According to the Gartland and Werley grading system, it was excellent for 13 patients, good for 11 patients, and moderate for one patient. According to Green and O'Brien criteria, it was evaluated as excellent for five patients, good for five patients, moderate for 14 patients, and poor for one patient. Kibar<sup>6</sup> found that the VAS score was 2.1, the mean grip strength was 25.2.

In Mayo wrist score, Kibar found five patients had excellent, six of them had good, six patients had satisfactory, and three patients had poor results. Medlock et al.<sup>14</sup> evaluated the clinical results of 18 patients who were treated for intraarticular distal radius fractures with a volar-dorsal combined plate. They observed the union was achieved in all fractures. Average ROM was measured as 64%. Proper alignment and length were obtained in all patients. The average grip strength was 71% on the opposite side. According to the Modified Green and O'Brien system, they had ten good, seven intermediate, and one bad result, with an average fast DASH score of 29. There was no wound infection, tendon rupture, or major nerve injury. One patient required skin grafting due to a volar wound closure problem. Sagefors et al.<sup>21</sup> reported the results of 74 patients who operated on combined volar - dorsal plates in their study. Average pronation was 94%, supination 94%, extension 76%, flexion 74%, grip strength 82% relative to the unaffected side. VAS was recorded as 0 at rest and two at the activity. The mean score of the Quickdash was 14.8. The mean Batra score was 88; radial angulation was 21 degrees; volar tilt was 2.5 degrees. None of the patients had tendon rupture or complex regional pain syndrome. In 2 patients, oral therapy was administered due to the infection, and the dorsal plaque was removed due to dorsoradial wrist pain and extensor tenosynovitis in 21 of 74 patients. In our study, all fractures were healed. In mean joint ROM of our patients, flexion was 50, extension was 53, supination-pronation was 147 degrees. Mean grip strength was 80% compared to opposite side. Mean DASH score was 10.87, mean VAS score was 2.13. In Mayo classification, 7 patients were excellent and 6 patients were satisfactory in our study. There was no implant irritation, tendon rupture, infection and major nerve damage in our study. In three patients, there was transient reflex regional pain syndrome, which was improved by conservative treatment. Our findings were consistent with the literature, and complication rates were also lower than the others. Wei et al.<sup>22</sup> found that external fixation results in better grip strength, wrist flexion and remains a viable surgical alternative compared to ORIF. According to a meta-analysis, Xie et al.<sup>23</sup> analyzed DASH and grip strength of external fixation in three, six, and 12 months postoperatively. They stated that; DASH scores were between 123 and 147, and grip strengths were between 169 and 271 in approximately 35 studies. And 12-month radiological results were also similar. They stated the patients, who were operated on with external fixation, had minor and major complications, such as finger stiffness, tendon rupture, infection, complex regional pain syndrome, malunion, and non-union. In our study, all fractures were healed. We found flexion as 42 degrees, extension as 45 degrees, and pronation-supination as 145 degrees. DASH score was 14.92, and VAS score was 2.61. In Mayo classification, eight patients were excellent, and two patients were satisfactory. Grip strength was 87% compared to the opposite side. There were six patients with complex regional pain syndrome, seven patients with pin site infection, and three patients with finger stiffness in our study. Roh et al.<sup>24</sup> stated that there were no significant differences in grip strength, motion, or functional scores between patients operated with the volar plate and external fixation groups at 12 months. And also, the volar plate group showed superior short-term results for functional recovery. In another study, Richard et al.<sup>25</sup> found that volar plate fixation has an overall decreased incidence of complications and significantly better motion in flexion-extension and supination-pronation than external fixation. Rizzo et al.<sup>26</sup> evaluated 55 patients with distal radius. They stated that grip and range-of-motion data were similar, DASH scores, frequency of rehabilitation, and some radiographic parameters were superior in patients treated with ORIF. In a prospective study by Greval et al.<sup>27</sup>, the results of 62 patients operated with the dorsal plate and external fixation pinning due

**Table 3.** Grip strength values of patients.

Grip Strength	Group 1 n: 23		Group 2 n: 26		TOTAL n: 49		p-value
	Mean	SD	Mean	SD	Mean	SD	
Operated side	27.87	8.84	30.84	11.07	29.44	10.10	0.302
Opposite side	34.78	8.23	35.07	10.64	34.93	9.49	0.914
p-value	<0.001*		<0.001*		<0.001*		

SD: standard deviation. \* Paired samples t-test.

to AO type C distal radius fracture were compared. DASH score was not significantly different. There were higher complications in the dorsal plate group. The dorsal plate group also had higher pain levels at one year than the external fixator group; however, the pain level became equal after the plaque was removed. The external fixator group showed an average of 97% grip strength than the normal and 86% in the dorsal plate group. Wang et al.<sup>28</sup> investigated 895 patients by questioning the patients who were operated on with external fixator nailing or dorsal bridging plate for distal radius fractures. It was reported that the infection rate and complex regional pain syndrome were lower in dorsal bridge coverage. Gartland and Werley scores were better on the dorsal bridge plate. There was no significant difference in the DASH score and radiographic parameters. When we compared external fixation and combined volar-dorsal plate; grip strength, joint ROM, DASH and VAS scores were similar in our study. Radiological parameters were better in combined volar-dorsal plate group. Complication rates were lower in combined volar-dorsal plate group. Since we used the extensor retinaculum tendon to cover it over the plate after dorsal plate fixation, tendon rupture was rare. Rehabilitation time was longer in external fixation group. Infection rate was lower in combined plate group.

Early range of motion exercises and the advantage of mobilization are some advantages of the combined volar-dorsal plate. Complication rates were higher in the external fixation group. In the literature, dorsal plates with thicker profiles resulted in higher complication rates. In our study, we performed dorsal reduction

and fixation with plates with a thinner profile. So, we observed lower complication rates with mini-plate for fixation. Operation time was lower in the external fixation group compared to the combined dorsal-volar plate group. But, despite external fixation is a more comfortable procedure, the combined dorsal-volar plate needs a more experienced surgical technique.

The present study had some limitations. Our study had a retrospective design. The patient number was small. Surgical techniques were chosen according to surgeons' preferences. The number of patients with Type 4 fractures according to the Melone classification was relatively higher in the external fixation group. The follow-up period of our study included the mean follow-up of three years, which is another limitation. A longer-term follow-up of the procedure was required to detect tendon rupture or degeneration.

## CONCLUSION

In conclusion, we found similar functional results in treating intra-articular distal radius fractures with the combined volar-dorsal plate osteosynthesis and external fixation. The combined volar-dorsal plate osteosynthesis could be an alternative to external fixation because they have lower complication rates and permit early mobilization.

## ACKNOWLEDGEMENTS

We thank Kibar B. for his very important suggestions, contributions, and writing assistance.

**AUTHORS' CONTRIBUTION:** Each author made significant individual contributions to the development of this manuscript. Polar O: writing and performing surgeries; Toy S: data analysis and performing surgeries; Özbay H: review of the article and intellectual concept of the article.

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# SURGICAL TREATMENT OF ACROMIOCLAVICULAR DISLOCATION: HOOK PLATE VERSUS SUTURE BUTTON

## TRATAMENTO CIRÚRGICO DA LUXAÇÃO ACROMIOCLAVICULAR: LACA DE GANCHO VERSUS BOTÃO DE SUTURA

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### ABSTRACT

**Objective:** We aimed to compare the functional and radiographical outcomes of reconstruction of acute unstable acromioclavicular joint (ACJ) dislocation using Hook Plate (HP) versus Suture Endobutton (SE) fixation techniques. **Methods:** Forty-six consecutive patients with grade III to V ACJ dislocation according to Rockwood classification who underwent either HP or SE fixation in the period between January 2017 and June 2020 were evaluated. The treatment modalities were divided into either HP or SE fixation. The radiological assessment included standard anterior-posterior (AP) views to evaluate coracoclavicular (CC) distances for vertical reduction. **Results:** CC distances were grouped as preoperative (CC<sup>1</sup>), early postoperative (CC<sup>2</sup>), and late postoperative (CC<sup>3</sup>). The distance variance between CC<sup>2</sup> and CC<sup>3</sup> was referred as  $\Delta$ CC (CC<sup>3</sup> - CC<sup>2</sup>). A statistically significant difference was found in  $\Delta$ CC between the two groups ( $p=0.008$ ).  $\Delta$ CC was significantly higher in the SE group compared to the HP group ( $p<0.05$ ). The Constant and UCLA Scores of patients in the SE group were found to be significantly higher than in the HP group patients. **Conclusion:** Clinical outcomes were more satisfactory in patients with acute unstable ACJ dislocation who underwent SE compared to HP procedures, at the end of the first year. **Evidence Level IV; Case Series.**

**Keywords:** Acromioclavicular Joint; Surgical Procedures; Clavicle; Joint Dislocations.

### RESUMO

**Objetivo:** Nosso objetivo foi comparar os resultados funcionais e radiográficos da reconstrução da luxação instável aguda da articulação acromioclavicular (ACJ) utilizando técnicas de fixação com placa com gancho (HP) versus botão de sutura (SE). **Métodos:** 46 pacientes com luxação da ACJ de grau III a V, de acordo com a classificação de Rockwood, que foram submetidos à fixação com HP ou SE no período de janeiro de 2017 a junho de 2020, foram avaliados. As modalidades de tratamento foram divididas em fixação HP ou SE. Na avaliação radiológica, foi utilizada a incidência antero-posterior (AP) para avaliação da redução vertical, por meio da medida da distância córaco-clavicular (CC). **Resultados:** As distâncias CC foram agrupadas em pré-operatória (CC<sup>1</sup>), pós-operatória imediata (CC<sup>2</sup>) e pós-operatória tardia (CC<sup>3</sup>). A variação da distância entre (CC<sup>2</sup>) e (CC<sup>3</sup>) foi denominada  $\Delta$ CC. Uma diferença estatisticamente significativa foi encontrada no  $\Delta$ CC entre os dois grupos ( $p=0,008$ ). O  $\Delta$ CC foi significativamente maior no grupo SE em comparação com o grupo HP ( $p < 0,05$ ). As pontuações de Constant e UCLA dos pacientes do grupo SE foram significativamente mais elevadas do que as dos pacientes do grupo HP. **Conclusão:** Os resultados clínicos foram mais satisfatórios com a técnica SE em comparação com a HP ao final do primeiro ano. **Nível de Evidência IV; Série de casos.**

**Descritores:** Articulação Acromioclavicular; Procedimentos Cirúrgicos; Clavícula; Luxações Articulares.

**Citation:** Dursun M, Altun G, Ozsahin M. Surgical treatment of acromioclavicular dislocation: hook plate versus suture button. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 5. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Acromioclavicular joint injuries are approximately 12% of all shoulder injuries and most commonly occurs by a direct force to the acromion under an adducted arm.<sup>1,2</sup> The ACJ is an important structure connecting the axial skeleton to the upper extremity, the upper extremities being suspended by strong coracoclavicular (CC) ligaments and an acromioclavicular (AC) ligament. Thus, dislocation with torn AC and CC ligaments often leads to severe functional impairment of

the injured shoulder. Due to the limited healing potential of the CC ligament, appropriate treatment is necessary in the acute phase.<sup>3</sup> Treatment of ACJ dislocations remains a controversial topic. There is a general consensus in the literature to treat acute Rockwood grade I and II injuries conservatively and grade IV, V and VI injuries operatively.<sup>4</sup> However, treatment of acute grade III injuries remains controversial.<sup>4,5</sup> Early surgical repair of grade III ACJ dislocations results in better outcomes and an earlier return to sport activities,

All authors declare no potential conflict of interest related to this article.

The study was conducted at the EPC Special Hospital, Department of Orthopedics and Traumatology, Adana, Turkey.

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Article received on 06/03/2021, approved in 05/04/2022.



although conservative treatment is also recommended.<sup>6-8</sup> Multiple surgical options exist, including CC screws, hook plates (HP), suture endobutton (SE) CC fixations, and anatomic ligament reconstructions with tendon grafts, but none can be regarded as the gold standard treatment.<sup>9</sup> The HP fixation technique is an effective treatment option for ACJ dislocation and is widely used owing to the simplicity of the surgical technique along with good clinical outcomes.<sup>10,11</sup> It also has the advantage of attaining reduction in the horizontal and vertical planes.<sup>12</sup> However, several documented complications have been reported, such as shoulder impingement, rotator cuff lesion, infection and bony erosion.<sup>13</sup> Eventually improved implants that are less invasive have been developed. These include the SE technique, which consists of a suspensory fixation device between the clavicle and the coracoid process that can stabilize the ACJ and reinforce the CC ligaments. Numerous studies have shown favorable clinical and radiographic results from this procedure.<sup>13</sup> In the literature, several comparative studies have aimed to evaluate treatment outcomes for ACJ dislocation with HP versus SE fixation techniques.<sup>13-18</sup> The clinical results of both surgical techniques have been satisfactory, although there is no clear consensus on which method produces superior outcomes. In the present study, we aimed to compare the functional and radiographical outcomes of reconstruction of acute unstable ACJ dislocation using HP versus SE fixation techniques.

## MATERIAL AND METHODS

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from each participant included in the study. The study was approved by the Ethics Committee of the same hospital (Decision no: 228 dated: 03.03.2021). No approval from the National Ethics Committee was necessary as it was a non-interventional observational study.

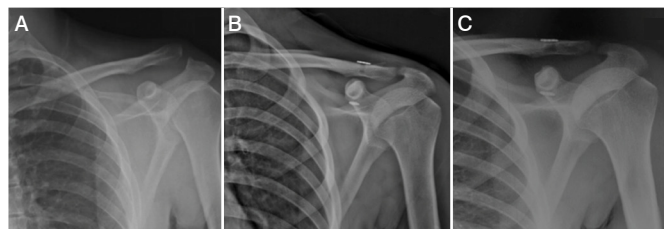
104 consecutive patients with grade III to V ACJ dislocation (according to Rockwood classification measured with true AP projection) who underwent either HP or SE fixation at our clinic in the period between January 2017 and June 2020 were compared and evaluated retrospectively. The inclusion criteria for the study were as follows: (1) no history of shoulder injuries or related surgeries, (2) acute ACJ dislocation (<2 weeks after trauma) of Rockwood type III or higher (3) A follow-up period of at least 12 months. The following patients were excluded: (1) open or chronic dislocations, (2) dislocations combined with neurovascular or vital organ injury, and (3) ipsilateral upper limb fractures and/or dislocations. The treatment modalities were divided into either HP or SE fixation and all surgeries were performed by two senior surgeons. Each surgeon performed only HP or SE technique. Sixty-two patients were treated using HP fixation while 42 patients were treated with the SE technique. Of the 104 patients initially screened, 58 met one or more of the exclusion criteria or did not meet inclusion criteria; therefore, the remaining 46 patients (23 HP and 23 SE) were included in the final study group. The surgical method was decided according to surgeon's preference and experience.

Demographic and clinical data regarding age, sex, hand dominance, mechanism of injury, time from trauma to surgery, time from surgery to the return to daily activities, and length of follow-up were collected. A functional assessment was performed by two independent reviewers using the Constant score and University of California Los Angeles (UCLA) score. Radiological assessment included standard anterior-posterior (AP) views to evaluate CC distances for vertical reduction. The CC distance was defined as the vertical distance between the anterior-inferior border of the clavicle and the superior border of the coracoid process. All measurements were performed

and analyzed in three stages: preoperatively, in the early postoperative period, and at the time of the final follow-up. The affected ACJ was also evaluated for any signs of postoperative degenerative arthritis, loss of reduction, osteolysis and acromio-coracoclavicular ligament ossification. CC distances were grouped as preoperative (CC<sup>1</sup>), early postoperative (CC<sup>2</sup>) and late postoperative (CC<sup>3</sup>). The distance variance between CC<sup>2</sup> and CC<sup>3</sup> was referred as  $\Delta$ CC (CC<sup>3</sup> - CC<sup>2</sup>). Two criteria for radiological failure were identified in the current study. The first one was comparison of the CC distance measured immediately after the surgery and at the final follow-up. The second was comparison of CC distances measured on the operated side and on the unaffected side at the final follow-up.

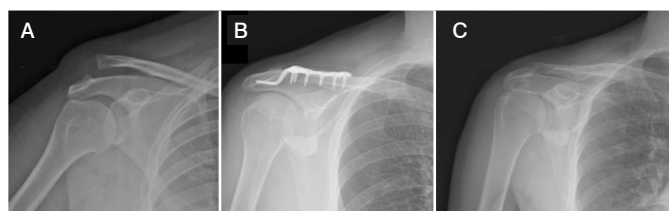
## Surgical Technique:

Patients were placed in the beach chair position under general anesthesia. The upper extremity was prepared and draped in the usual sterile manner, and appropriate antibiotic prophylaxis was administered before the incision. An approximately 6 cm incision was made at the superior end of the injured ACJ. For HP fixation, the patient's soft tissues were dissected until the ACJ became visible. Next, the anterior and posterior edges of the acromion were located, and their midpoint was marked to guide the placement of the plate. The ACJ dislocation was reduced, and a hook plate was placed over the ACJ. (Figure 1) The hook was placed as posteriorly as feasible to ensure complete attachment to the acromion and to avoid sub-acromial impingement (on the supraspinatus bursa or rotator cuff). For SE fixation, a 5 cm incision was made at the top of the clavicle, 2 cm medial to ACJ. The pectoral muscle was dissected out from clavicle and meticulous dissection was performed down to the base of the coracoid process. Under C-arm X-ray machine visualization, the bony tunnels to the clavicle and coracoid process were drilled during separate steps. First, a 2.4-mm guide pin was inserted in a cephalad to caudal direction at the base of the coracoid process. The guide pin was aimed at the center of the coracoid process and close to the neck. A 4.0-mm cannulated drill was used, and care was taken to avoid advancing the guide pin while drilling. Then, a bony tunnel was drilled in a similar manner at the center of the distance between the anterior and posterior borders of the clavicle. The guide wire and drill were removed; the suture button was inserted through the clavicle, and then through the coracoid tunnel using the button inserter. The oblong button was flipped and seated underneath the coracoid process using a pusher. Finally, the ACJ was reduced and placed in the anatomical position under fluoroscopic visualization, and the round button was advanced to the cephalad surface of the clavicle. (Figure 2) The subcutaneous tissues and skin were closed in the usual manner. After surgery, a standard rehabilitation program was applied to all patients, with the use of a shoulder immobilizer sling for 4 weeks. The patients were allowed to start gentle pendulum & Codman's exercises and perform elbow flexion & extension exercises



**Figure 1.** A) Preoperative left shoulder XR of 47 years old male patient with Type 3 acromioclavicular dislocation B) Early postoperative XR of patient who underwent suture endobutton (SE). An overcorrection of the coracoclavicular distance can be observed. C) Postoperative XR of the same patient at the end of a one-year follow up. Resolution of the overcorrection of coracoclavicular distance can be observed.





**Figure 2.** a) Preoperative right shoulder XR of 42 years old male patient with type 5 acromioclavicular dislocation b) Early postoperative XR of the patient who underwent hook plate (HP) c) Postoperative XR of the same patient after HP removal.

as tolerated postoperatively. In the fourth week, the arm sling was removed, and stretching exercises were conducted to increase the range of motion; while strengthening exercises were started after 8 weeks. Standard exercises in a home exercise program were recommended. Full active movement was allowed at 6 weeks and a return to manual work was allowed at 2 months. Contact sports were not allowed until 6 months postoperatively.

### Statistical Analysis

Statistical analyses were carried out with IBM SPSS (Statistical Package for the Social Sciences for Windows, version 21.0, Armonk, NY, IBM Corp.). Frequency tables and descriptive statistics were used to interpret the findings. Parametric methods were used for measurement values suitable for normal distribution. Shapiro-Wilk test was used for measurement of normal distribution. In accordance with the parametric methods, the "Independent Sample-t" test (t-table value) method was used to compare the measurement values of the two independent groups. Nonparametric methods were used for measurement values that were not suitable for normal distribution. In accordance with non-parametric methods, "Mann-Whitney U" test (Z-table value) method was used to compare the measurement values of two independent groups. The "Friedman" test ( $\chi^2$ -table value) method was used to compare the measurement values of three or more dependent groups. Dunn correction was applied for paired comparisons of variables that differed significantly for three or more groups. "Spearman" correlation coefficient was used to examine the relationship between two quantitative variables that did not have a normal distribution. "Pearson- $\chi^2$ " and continuity correction cross tables were used to examine the relationship between two qualitative variables. For each measurement, the interclass correlation coefficient (ICC) and 95% confidence interval were reported. Correlation was classified as poor (0.00–0.20), fair (0.21–0.40), moderate (0.41–0.60), good (0.61–0.80), or excellent (0.81–1.00).

### RESULTS

All patients had an ACJ dislocation and underwent fixation with either HP or SE technique. The average age of the SE group was  $38.17 \pm 12.34$  years and the HP group was  $48.69 \pm 13.55$  years. No statistically significant differences in age, sex, affected side, dominant limb, trauma mechanism or distribution of Rockwood classification were found between the two groups ( $p > 0.05$ ). The groups were found to be independent and homogeneous for the specified characteristics. Detailed data are presented in Table I. There was no statistically significant difference in CC<sup>1</sup>, CC<sup>2</sup> or CC<sup>3</sup> distances between the groups ( $p > 0.05$ ). A statistically significant difference was found in  $\Delta$ CC ( $Z = -2.652$ ;  $p = 0.008$ ) between the two groups.  $\Delta$ CC was significantly higher in the SE group compared to the HP group ( $p < 0.05$ ) (Table II). ICC of the observers for the radiological measurements was 0.89 which showed excellent reliability. The Constant and UCLA Scores of patients in the SE group were  $97.65 \pm 2.87$  and  $38.70 \pm 1.30$  and for the HP group they were  $94.59 \pm 3.06$  and  $34.14 \pm 1.73$ , respectively. Clinical scores of patients

in the SE group were found to be significantly higher than those of the patients in the HP group ( $Z = -3.495$ ;  $p = 0.000$ ,  $Z = -5.718$ ;  $p = 0.000$ , for SE and HP, respectively) (Table III). A modest but statistically significant correlation was found between  $\Delta$ CC differences and the Constant or UCLA Score in the SE group ( $p < 0.05$ ). As the Constant or UCLA scores increased, the  $\Delta$ CC showed a decrease. Likewise, as the Constant and UCLA scores decreased, the  $\Delta$ CC value increased. No statistically significant correlation could be identified between  $\Delta$ CC and the Constant and UCLA Scores of the HP group ( $p > 0.05$ ) (Table IV).

**Table 1.** Characteristics of forty-six patients who underwent fixation of acromioclavicular joint dislocation with hook plate (HP) or suture endobutton (SE).

Group	SE (n=23)		HP (n=23)		Statistical analysis* Probability
Variable	n	%	n	%	
Age groups					
<30	8	34.9	8	34.8	$\chi^2=0.397$ p=0.941
30-39	5	21.7	3	13.0	
40-49	5	21.7	6	26.1	
≥50	5	21.7	6	26.1	
Gender					
Male	18	78.3	16	69.0	$\chi^2=0.190$ p=0.663
Female	5	21.7	7	31.0	
Limb					
Right	13	56.5	14	60.1	$\chi^2=0.023$ p=0.879
Left	10	43.5	9	39.9	
Dominant limb					
Right	22	95.7	17	73.9	$\chi^2=1.705$ p=0.192
Left	1	4.3	6	26.1	
Trauma					
Sport	7	30.4	6	26.1	$\chi^2=0.424$ p=0.935
Simple fall	10	43.5	10	43.5	
Bicycle accident	4	17.4	5	21.8	
Fall from height	2	8.7	2	8.6	
Rockwood status					
Type 3	9	39.1	6	26.1	$\chi^2=0.341$ p=0.559
Type 5	14	60.9	17	73.1	

\*"Pearson- $\chi^2$ " and continuity correction cross tables were used to examine the relationship between two qualitative variables.

**Table 2.** Comparison of CC distances of patients who underwent fixation of acromioclavicular joint dislocation with either hook plate (HP) or suture endobutton (SE).

Group	SE (n=23)		HP (n=23)		Statistical analysis* Probability
Variables	X	S.S.(cm)	X	S.S.(cm)	
		Median [IQR]		Median [IQR]	
$\Delta$ CC	0.82	0.70	0.45	0.30	$Z = -2.652$ $p = 0.008$
<b>CC distance</b>					
CC <sup>1</sup>	21.23	4.24	21.91	3.64	$Z = -0.194$ $p = 0.846$
CC <sup>2</sup>	10.71	1.10	10.42	1.37	$Z = -1.230$ $p = 0.219$
CC <sup>3</sup>	11.53	1.32	10.87	1.45	$t = 1.681$ $p = 0.099$
Statistical analysis Probability	$\chi^2=46.000$ $p=0.000$ [1-2.3] [2-3]		$\chi^2=56.214$ $p=0.000$ [1-2.3] [2-3]		

\*"Independent Sample-t" test (t-table value) statistics was used to compare the measurement values of two independent groups with normal distribution. "Mann-Whitney U" test (Z-table value) was used for the comparison of measurement values of two independent groups that did not have normal distribution; "Friedman" test ( $\chi^2$ -table value) statistics were used to compare three or more dependent groups.

**Table 3.** Comparison of parameters according to the groups.

Group Variable	Endobutton (n=23)		Hook Plate (n=23)		Statistical analysis* Probability
		Median [IQR]		Median [IQR]	
Follow-up time	19.70±4.85	19.0 [8.0]	26.07±9.15	25.0 [17.0]	Z=-2.261 p=0.024
Constant score	97.65±2.87	98.0 [4.0]	94.59±3.06	94.0 [4.0]	Z=-3.495 p=0.000
UCLA score	38.70±1.30	39.0 [2.0]	34.14±1.73	34.0 [2.0]	Z=-5.718 p=0.000

\*"Mann-Whitney U" test (Z-table value) statistics were used in comparing the measurement values of two independent groups with no normal distribution.

**Table 4.** Correlation analyses between  $\Delta$ CC and two different functional scores of patients who underwent fixation of acromioclavicular joint dislocation with hook plate (HP) or suture endobutton (SE).

Group	$\Delta$ CC differences			
	SE (n=23)		HP (n=23)	
	r	p	r	p
Constant score	-0.438	0.036	-0.272	0.153
UCLA score	-0.445	0.033	0.047	0.809

\*Spearman correlation coefficient was used to examine the relationship between two quantitative variables that did not have normal distribution.

## DISCUSSION

In the current study, the radiological and clinical scores of patients with ACJ dislocation who underwent either HP or SE fixation were evaluated. A statistically significant increase in the CC distance was identified in patients who underwent SE fixation. However, at the final follow up after at least 12 months, the UCLA and Constant scores were lower in the HP group.

HP fixation is a dynamic technique for the surgical fixation of ACJ dislocation. It works on the principle of generating a leverage arm through the proximal end of the plate to the acromion as a dynamic fixation and can hold the position of the clavicle and CC distance stable. This technique can be used with satisfactory results to treat acute injuries and may be combined with ligament reconstruction for chronic injuries as well. However open reduction and internal fixation with HP may cause postoperative complications such as subacromial osteolysis, rotator cuff rupture, acromial fracture or impingement syndrome.<sup>16-19</sup> Furthermore, the fact that HP causes limitation and pain in shoulder movements after a period of time entails the need to remove it with a second surgery. This has negative effects on the rehabilitation process and the eventual clinical outcome. In the cases examined in the current study, acromial osteolysis was detected in only two patients and the implant was removed at the seventh and eighth months. The mean duration of postoperative time up to implant removal for the rest of the patients was six months. We attribute the low complication rate of this study to the short duration of retention of the implant with the HP technique. In the literature, the complications of SE technique include loss of reduction, coracoid process fracture, implant failure and overcorrection. In the cases included in the current study, overcorrection was detected in only one patient and the final outcome according to the clinical scores at the follow-up period was excellent (Constant: 100, UCLA: 40)

The SE technique has been reported to be applied not only with two endobuttons, one for clavicle and one for coracoid separately. Furthermore, different fixation technics were described as, Twin Tail Tight Rope<sup>®</sup>, with two endobuttons for the clavicle and one button for coracoid; Double Tight Rope<sup>®</sup> two endobuttons for the clavicle and two buttons for coracoid.<sup>4,20</sup> These enhanced techniques can provide horizontal stability with the fiber wire in the ACJ.<sup>4</sup> However,

with these non-physiological fixation methods, increased stiffness can cause implant failure in coracoid fixation (20). Nonetheless, in comparative studies, vertical and horizontal stability of the double endobutton technique was described to be better than the single system; however, there was no significant difference in the clinical scores and the CC distance.<sup>21</sup> In the current study, the increase in CC distance at the one-year follow up did not have a negative effect on clinical scores in the SE group as well.

In a meta-analysis, Weihui et al. suggested that the SE technique showed better outcomes compared to the HP technique in functional recovery and pain. The same study showed that when the CC distances were evaluated radiologically, an acceptable reduction loss was observed with the SE technique.<sup>22</sup> In another meta-analysis, Wang et al. reported that the SE technique showed functionally better results compared to the HP technique; however no statistically significant difference in CC distance and complications could be identified.<sup>13</sup> In the current study, we identified a statistically significant increase in CC distance between the first measurement at the early-postoperative period and the next measurement at the first-year follow-up in patients treated with the SE method compared to the patients treated with the HP method. But a modest significant correlation was found between clinical scores and  $\Delta$ CC differences in SE group. This may have resulted from the development of complications in the HP patients despite the removal of the plate after a short time. Although both SE and HP are dynamic techniques, the support point of HP is the subacromial face of the acromion and it was shown that horizontal and vertical plate movements in this area cause mechanical trauma in both inferior border of the acromion in the superior area and bursal side of the rotator cuff in the inferior area.<sup>19</sup>

A direct relationship between the  $\Delta$ CC and Constant/UCLA scores was detected in the SE group. These parameters have a reciprocal relationship with each other. Of note, no statistically significant relationship was identified between  $\Delta$ CC and clinical scores in the HP group. However, the lack of a statistically significant relationship does not necessarily lead to an interpretation of no relationship between  $\Delta$ CC and clinical satisfaction in the HP group. In fact, the change in  $\Delta$ CC in the HP group was very small, which precluded the establishment of a relationship between  $\Delta$ CC and clinical scores. Rather, the bigger change in  $\Delta$ CC in patients in the SE group allowed the establishment of relationship with clinical scores that reached statistical significance.

A cost analysis of both surgical techniques in our health care system indicated that the implant and material costs of both HP and SE techniques were comparable. However, the need for a second surgery with the use of HP enhanced the overall costs. These costs may differ from region to region and with health policies; nonetheless, the decision for use of either technique during surgery may be influenced by the prevalent economic conditions and secondary surgical risk factors relevant to the patient's health.

The limitations of the study that need to be considered are as follows: The current study is not the first one to compare the outcomes of use of either of SE or HP techniques, there are several studies in the published literature that have reported such comparisons. However, technical improvements such as fixation material technology and surgical choices have been updated during the last decade. Furthermore, recent developments may affect clinical scores and radiological outcomes. Secondly, horizontal stability has not been assessed for either group of patients in the current study. Recent studies have indicated that vertical stability is more significant in affecting clinical scores than horizontal stability; in addition, too much stiffness of implant fixation may result in failure.

## CONCLUSION

Both SE and HP techniques offered beneficial outcomes in relieving pain of dislocation and improving function of ACJ at the end of one-year follow-up in the postoperative period. A significant increase

in CC distance was detected in the SE group at the end of the first year compared to the HP group; clinical outcomes were also more satisfactory with SE compared to HP.

**AUTHORS' CONTRIBUTION:** Each author made significant individual contributions to the development of this manuscript. Dursun M: writing, data analysis and performing surgeries; Ozsahin M: data analysis and performing surgeries; Altun G: writing, review of the article and intellectual concept of the article.

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# THORACOLUMBAR BURST FRACTURES: SHORT FIXATION, WITHOUT ARTHRODESIS AND WITHOUT REMOVAL OF THE IMPLANT

## FRATURA TORACOLUMBAR EXPLOSÃO: FIXAÇÃO CURTA, SEM ARTRODESE E SEM A RETIRADA DO IMPLANTE

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### ABSTRACT

**Objectives:** To present the functional outcomes, through the first case series in our country, of patients with thoracolumbar burst fractures (A3,A4), submitted to short posterior fixation, without arthrodesis and without removal of the implants, until the end of the minimum follow-up of one year. **Methods:** Fifty five patients consecutively treated between January/2010 and January/2019 were evaluated through medical records and imaging exams. Radiographic analysis was performed by measuring local and segmental kyphosis using the Cobb method. Functional assessment was analyzed using the non-specific SF-36 questionnaire and the 1983 Denis pain and work-specific questionnaire, applied after 12 months of follow-up. **Results:** With a loss of five patients (9%), 22 (44%) patients reported having minimal and occasional pain and 8 (16%) patients reported having no pain. Three (6%) patients responded that they were completely incapacitated. Patients had a mean score of 73.16 points in the SF-36 domains. There was a significant reduction in kyphosis in 12 months ( $9.1 \pm 5.2$  [min-max 0-22]) compared to the preoperative period ( $14.9 \pm 7.8$  [min-max 0-32]) ( $p \leq 0.01$ ). One patient required implant removal due to the symptomatic prominence of the implant. **Conclusion:** This case series suggests that the technique leads to satisfactory functional results, without implant failure or significant kyphosis after a minimum follow-up of 12 months of treatment. **Evidence Level IV; Case series.**

**Keywords:** Accidents; Thoracic Vertebrae; Lumbar Vertebrae; Arthrodesis.

### RESUMO

**Objetivos:** Apresentar os desfechos funcionais, mediante primeira série de casos no nosso meio, de pacientes com fratura toracolumbar do tipo explosão (A3, A4), submetidos a fixação posterior curta, sem artrodeose e sem retirada dos implantes, até o final do acompanhamento mínimo de um ano. **Métodos:** Foram avaliados, por meio de prontuários e exames de imagem, 55 pacientes consecutivamente tratados entre Janeiro/2010 e Janeiro/2019. A análise radiográfica foi realizada medindo a cifose local e segmentar, pelo método de Cobb. A avaliação funcional analisada por meio do questionário inespecífico SF-36 e questionário específico de dor e trabalho de Denis de 1983, aplicados após os 12 meses de seguimento. **Resultados:** Com perda de cinco pacientes (9%), 22 (44%) pacientes relataram ter dor mínima e ocasional e 8 (16%) pacientes responderam não ter dor. Três (6%) pacientes responderam que estavam completamente incapacitados. Os pacientes tiveram uma pontuação média de 73,16 pontos nos domínios do SF-36. Houve redução significativa da cifose em 12 meses ( $9,1 \pm 5,2$  [min-máx 0-22]) na comparação com o pré-operatório ( $14,9 \pm 7,8$  [min-máx 0-32]) ( $p \leq 0,01$ ). Um paciente necessitou de retirada do implante em razão da proeminência sintomática do implante. **Conclusão:** Esta série de casos sugere que a técnica leva a resultados funcionais satisfatórios, sem falha do implante ou cifose pós-traumática após acompanhamento mínimo de 12 meses de tratamento. **Nível de Evidência IV; Série de casos.**

**Descritores:** Acidentes; Vértébras Torácicas; Vértébras Lombares; Artrodeose.

**Citation:** Moreira CHT, Krause Neto W, Meves R. Thoracolumbar burst fractures: short fixation, without arthrodesis and without removal of the implant. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 5. Available from URL: <http://www.scielo.br/aob>.

All authors declare no potential conflict of interest related to this article.

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Article received on 06/27/2021, approved in 03/08/2022.





## INTRODUCTION

The thoracolumbar transition is most affected by fractures of the spine as it is a region located between the less flexible thoracic spine and the more flexible lumbar spine.<sup>1</sup>

Burst fractures are one of the most common types of fractures of the thoracolumbar spine, mainly caused by trauma mechanisms in the axial direction, ranging from 21 to 64% of all thoracolumbar fractures.<sup>2</sup> Studies show that the short posterior fixation with screws in the fracture is enough to obtain stability, avoiding the need for instrumented fusion of the long segment.<sup>3,4</sup> However, there still seems to be no consensus regarding the long-term results.<sup>5</sup>

Despite the development of biomechanical studies and new instrumentation systems, clinical studies still discuss the most appropriate surgical procedure to treat burst fractures since ventral, dorsal and combined instrumentation are available,<sup>5</sup> long or short fixation, with or without intermediate screw.

Furthermore, the fusion or arthrodesis of the fixed segment may or may not be performed, even if there are studies that demonstrate that there is no clinical and radiographic difference in the results.<sup>2</sup> In view of the lack of consensus and the scarcity of studies on fixation without arthrodesis and without removing implants in our country, we proposed a series of cases with short fixation without arthrodesis to analyze the clinical and radiographic outcomes, with a minimum follow-up of one year.

Therefore, the aim of this study was to analyze the functional and radiographic outcomes of patients with thoracolumbar burst fractures according to AO (A3/A4), treated with short fixation via the posterior approach, without arthrodesis and without removal of the implants until the end of the minimum follow-up of 12 months.

## MATERIALS AND METHODS

This study was approved by the Research Ethics Committee of Santa Casa de São Paulo, under protocol number 2.573.255, and by the Management Committee for Internships, Projects, Research, Extensions and Work – CGEPET, from the Dourados Health Services Foundation – FUNSAUD, by letter of authorization. All patients included in this study read and signed an informed consent form. Of a total of 55 patients, five lost follow-up during follow-up. Therefore, 50 patients completed the study (38 males and 12 females). The mean follow-up period for patients was  $14.5 \pm 12.4$  months (ranging from 12 to 60 months).

This study is a retrospective analysis of consecutive case series, using medical records and imaging exams (x-ray [XR] and computed tomography [CT]), with data from pre- and postoperative assessments of patients with thoracolumbar burst fractures type A3 and A4, according to the AOSpine classification.<sup>6,7</sup> Patients without neurological deficit underwent short posterior fixation, without arthrodesis, with a screw in the fractured vertebra, according to the technique described by Kanna et al.<sup>8</sup>

Inclusion criteria were: thoracolumbar burst fractures classified as A3 and A4 by AOSpine, without neurological deficit, acute, which underwent surgical treatment with short fixation, including the fractured vertebra, without arthrodesis.

Exclusion criteria were: multiple-level fractures, fractures caused by other diseases, fractures not classified as A3 or A4, cases with arthrodesis or with a larger fixed segment, patients with neurological deficit, patients with less than one year of follow-up, incomplete medical record, lack of radiographs at the beginning and end of follow-up, loss of follow-up or non-acceptance to participate in the study.

The variables studied were age, gender, level affected, pre- and postoperative Cobb angles (1948) and neurological status according to the Scale by Frankel et al (1969).<sup>9,10</sup>

The primary functional outcomes evaluated in this study were pain and postoperative functional capacity, according to the criteria of Denis (1983). As a secondary outcome, quality of life was assessed according to the SF-36 validated for the Portuguese language.<sup>11,12</sup> The patients underwent functional analysis based on the Denis Pain and Work Scale<sup>13</sup> and the Short-Form 36 (SF-36) quality of life questionnaire applied at the last follow-up.

Radiographic analysis was performed by measuring local and segmental kyphosis using the Cobb method.<sup>9,14</sup> To measure the segmental kyphosis (fixed segment), immediately preserved endplates, cranial and caudal at the affected level were used as reference. For local kyphosis (fractured vertebra), the end plates of the upper and lower fractured vertebrae were used for the measurement (Figure 1), according to the methodology applied by Siebenga et al.<sup>15</sup> The measurement was performed on lateral view radiographs performed on three occasions: at the initial diagnosis (baseline), in the immediate postoperative period (immediate) and at the end of the 12-month follow-up.

## Surgical technique

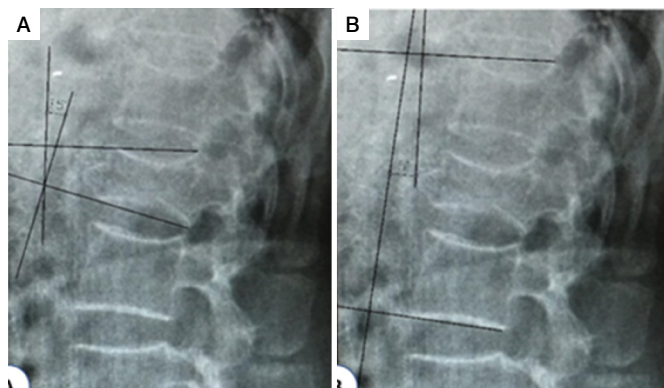
With the patients under general anesthesia and positioned in the prone position, a standard posterior midline incision was made. Using the technique of Kanna et al,<sup>8</sup> we started with the classic posterior exposure of the spine through the midline. The posterior ligament complex and the facet joint were preserved during the exposure.

The screw entry point in the pedicle was located, using the technique of Roy-Camille et al (1986), at the junction point of the transverse process and upper facet with a pointed perforator.<sup>16</sup> We used intraoperative radioscopy and polyaxial screws in all procedures. The placement of screws in the vertebrae above and below the fracture was started, with divergent inclination (Figure 2), so that when placing the longitudinal bars lightly molded in lordosis, bilateral distraction of the fracture was made, reducing the wedging of the fractured vertebra and the local and segmental kyphosis. The fractured vertebra was also screwed bilaterally.

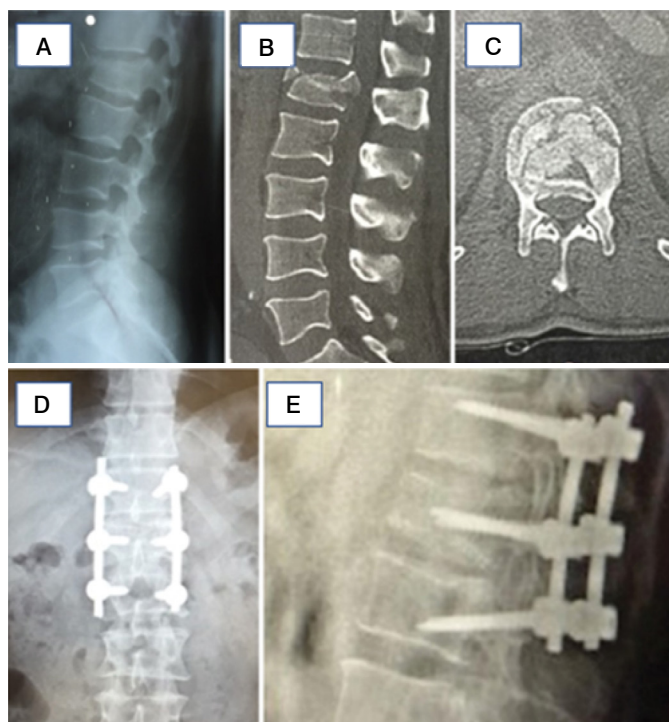
Through the ligamentotaxis mechanism, the reduction and decompression of the vertebral canal was carried out indirectly.<sup>1</sup> Thus, the reduction procedure included the following steps: improvement of the local and segmental kyphosis, lordotic distraction to reduce the vertebral height and the intra-canal fragment, and rigid block with the placement of counter screws.<sup>17</sup> The implants, in theory, should be removed after radiographic consolidation, which occurs on average six months after the fracture.

## Statistical analysis

For the final analysis of the data, descriptive statistics (mean, standard deviation, median and minimum-maximum values) were used.



**Figure 1.** Illustration of the Cobb angle (A - local kyphosis 15 degrees and B- segmental kyphosis 5 degrees).



**Figure 2.** Illustrative images of the pre (A, B, and C) and postoperative (D and E) periods of 12 months. A- Preoperative x-ray; B- Sagittal plane computed tomography; C- Axial plane computed tomography; D- Post-operative anteroposterior x-ray 12 months; E- Posterior post-operative X-ray 12 months.

To determine the normality of the sample, we used the Shapiro-Wilk test. As most of the variables did not have a normal distribution, non-parametric tests were chosen.

To compare the segmental and local kyphosis angles, the Friedman's non-parametric test was used. For comparison between the evaluated moments, the Wilcoxon test was applied. For the correlation between the Denis Pain and Work Scale scores and the SF-36 quality of life questionnaire, Spearman's correlation test was used.

The SPSS version 13.0 program was used to perform the statistical analysis of this work. The significance value was set at  $p \leq 0.05$ .

## RESULTS

Following the criteria for inclusion of fractures, 39 cases were classified as type A3 (78%) and 11 cases were classified as type A4 (22%).

### Pain and Work Scale

On the Denis Pain Scale, 22 patients (44%) reported minimal and occasional pain. Moderate pain was reported by 20 (40%) patients, but without interruption of daily activities or work. Other patients (16%) responded that they were without pain after one year of follow-up. (Table 1)

On the Denis Work Scale, 24 patients (48%) responded that they would be able to return to work (sedentary) or heavy work with restrictions. In addition to these, 12 (24%) patients responded that they felt able to return to previous work (heavy) or heavy physical activities. However, 11 (22%) patients reported that they felt unable to return to their previous job but were working full time in a new job, and only three (6%) patients responded that they were completely disabled. (Table 1)

### Evaluation of Segmental and Local Kyphosis

The analysis of segmental kyphosis showed a statistical difference between the evaluated moments ( $p \leq 0.01$ ). There was a smaller angle of segmental kyphosis in the immediate post-surgical moment ( $11.5 \pm 8.7$  [min-max 0-31]) compared to the baseline moment ( $13.3 \pm 8.5$  [min-max 0] -40]) and 12 months ( $13.2 \pm 7.8$  [min-max 2-36]) ( $p \leq 0.01$ , Figure 3).

The analysis of local kyphosis showed a statistical difference between the moments ( $p \leq 0.01$ ), with a significant reduction in the angulation in the immediate postoperative period ( $8.8 \pm 5.4$  [min-max 1-22]) and 12 months ( $9.1 \pm 5.2$  [min-max 0-22]) compared to baseline ( $14.9 \pm 7.8$  [min-max 0-32]) ( $p \leq 0.01$ , Figure 4).

One patient underwent removal of the synthesis due to pain and local discomfort in the prominence of the implant and reported, after three months of removal of the synthesis, an improvement in local pain and movement.

There were no cases of infection, implant failure, neurological deficit, or significant loss of correction until the end of follow-up.

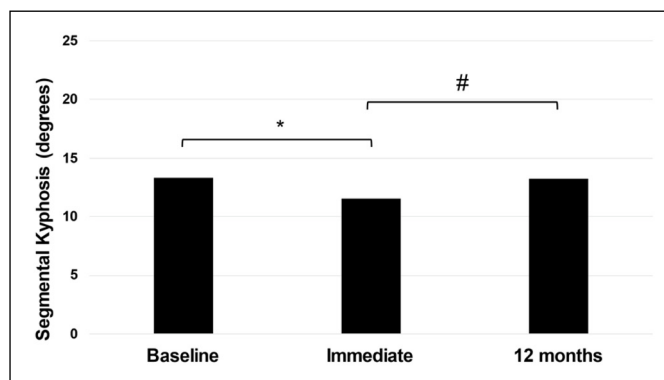
### Quality of Life Assessment

At the end of 12-month follow-up, patients scored above 70 in all SF-36 domains, with the exception of physical limitation ( $48.5 \pm 38.3$ ) and pain ( $69.8 \pm 14$ ). (Table 2)

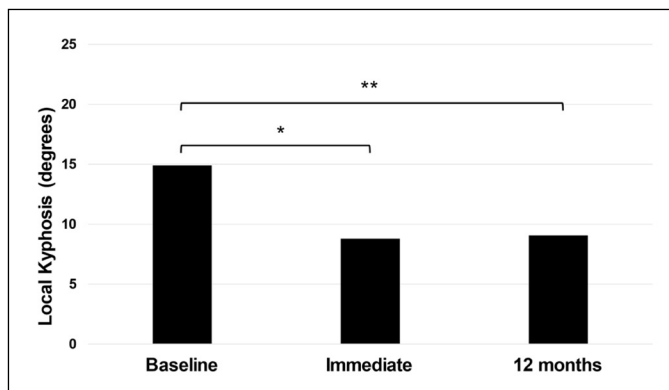
Correlation tests demonstrated an inverse relationship between the Denis Pain and Work Scale scores and many SF-36 domains. (Figure 5)

**Table 1.** Description of the frequency of responses regarding the Pain and Work scale of Denis (1983).

Criteria	Frequency (n <sup>o</sup> )	Percentage (%)
<b>Pain Scale</b>		
D1	8	16
D2	22	44
D3	20	40
D4	0	0
D5	0	0
Total	50	100
<b>Work Scale</b>		
T1	12	24
T2	24	48
T3	11	22
T4	0	0
T5	3	6
Total	50	100



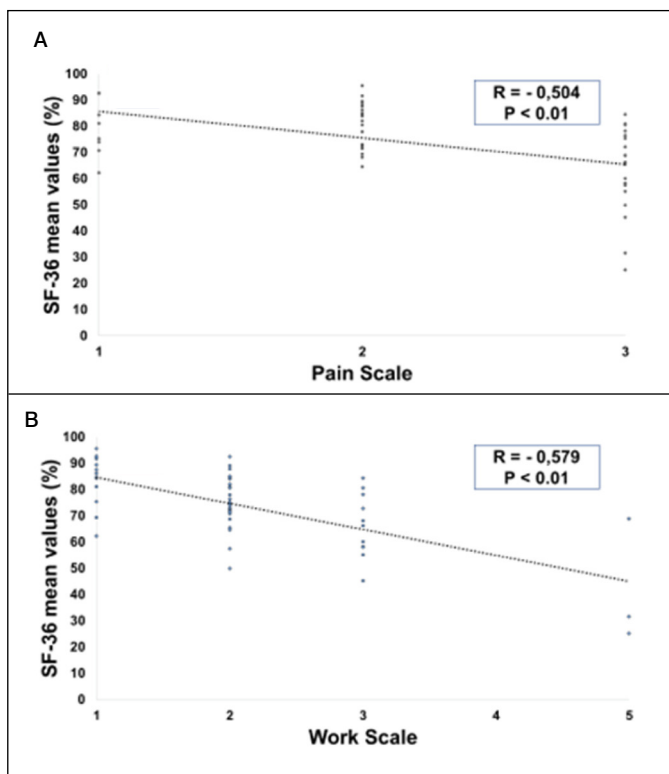
**Figure 3.** Comparison of the degrees of segmental kyphosis between the preoperative (Baseline), immediate postoperative (immediate), and 12 months postoperative (12 months) moments. Legend: \* statistically different from baseline; # statistically different than 12 months.



**Figure 4.** Comparison of degrees of local kyphosis between preoperative (Baseline), immediate postoperative (immediate), and 12 months post-operatively (12 months). Legend: \* statistically different from immediate; \*\*statistically different from 12 months.

**Table 2.** Description of the mean, median, standard deviation, and minimum-maximum values of the domains analyzed by the SF-36 questionnaire.

Domains	Mean	Median	Minimum	Maximum
Social Aspects	89.4	100.0	25.0	100.0
Mental Health	80.7	80.0	28.0	100.0
Emotional Limitations	75.9	100.0	0.0	100.0
Vitality	74.9	75.0	30.0	100.0
Functional capacity	74.1	75.0	15.0	100.0
General Health Status	72.0	72.0	52.0	100.0
Pain	69.8	74.0	30.0	100.0
Physical Limitation	48.5	50.0	0.0	100.0



**Figure 5.** Spearman correlation coefficient tests between Denis pain (A) and work (B) scale scores and general SF-36 questionnaire domains.

Regarding the eight domains evaluated in the SF-36 (Table 3), significant correlations were found between DD and CF, LF, DOR, EGS, AS and LE. Regarding TD, significant correlations were found with all SF-36 domains.

## DISCUSSION

Few studies have compared different treatments in a target population with neurologically intact A3 and A4 fractures.<sup>18</sup> According to Rometsch et al.,<sup>18</sup> although previous studies have shown a possible benefit of surgical treatment for fractures of types A3 and A4, there is no consensus. However, it is still difficult to discuss parts of these outcomes due to the great variability of measurement techniques. Furthermore, most studies do not differentiate fractures into incomplete (A3) and complete (A4).<sup>18</sup>

In this study, it was shown that after one year of follow-up, 84% of patients reported mild and moderate pain, and 72% said they would return to work despite the small loss of the final segmental kyphosis. Recently, Özbek et al.<sup>19</sup> reported that short fixation had better clinical results and faster fusion despite the loss of the final postoperative kyphosis. The studies corroborate our findings, whose segmental kyphosis decreased soon after surgery, despite the return to baseline values after 12 months.<sup>19-21</sup> In the study by Chou et al.,<sup>19</sup> the loss of segmental kyphosis was attributed to the loss of height of the injured intervertebral disc and not the progression of kyphosis in the fracture. These findings corroborate the results of this study, as local kyphosis remained practically stable for up to 12 months. Furthermore, despite the small loss in the final segmental kyphosis, there was no compromise in the clinical and functional results.

By analyzing the literature, studies have shown that there is no significant difference between treatments, with and without arthrodesis, after fixation of burst fractures with pedicle screws.<sup>22,21,02</sup> However, few studies have described the surgical treatment of thoracolumbar burst fractures using the posterior short fixation technique, including the fractured vertebra and without arthrodesis.<sup>22,08,17,23</sup> Our study adds information on outcomes without removing the synthesis material, which is routinely recommended for this technique after fracture healing. In our environment, it is argued that the vast majority of spinal surgery services do not follow the recommendation for removal of implants. The main reasons are the logistical difficulty for an elective vacancy and the non-adherence of the indication for removal of implants in asymptomatic patients. The observation of our patients showed that even without the removal of the implant in 49 patients, there was no case of infection, implant failure, neurological deficit or loss of the final significant correction until the end of follow-up. Wang et al. reported satisfactory results without fusion. However, the authors did not classify fractures as A3 and A4.<sup>22</sup> Furthermore, Kanna et al., in a retrospective analysis, were also not limited to fractures in A3 and A4, including patients with neurological deficit.<sup>8</sup> Reinforcing our results, Zhao et al. reported that the technique with intermediate screws can prevent the loss of postoperative kyphosis in patients without neurological deficit, as demonstrated here.<sup>17</sup> Finally,

**Table 3.** Spearman correlation coefficient tests between Denis pain [DP] and work [DW] scale scores and the SF-36 questionnaire domains (functional capacity [FC], physical limitation [PL], pain, general health status [GHH], vitality [VITA], social aspects [SA], emotional limitations [EL] and mental health [MH]).

		FC	PL	PAIN	GHH	VITA	SA	EL	MH
DP	Correlation	-0.634	-0.318	-0.632	-0.373	-0.259	-0.429	-0.292	-0.169
	P-value	0.000	0.025	0.000	0.008	0.069	0.002	0.040	0.241
DW	Correlation	-0.552	-0.319	-0.490	-0.460	-0.436	-0.417	-0.376	-0.465
	P-value	0.000	0.024	0.000	0.001	0.002	0.003	0.007	0.001



Liao and Fan described a group of patients with type A3 fractures, operated with short fixation, including the fractured vertebra and without arthrodesis, as in our study, but they did not include type A4 fractures, as we did.<sup>23</sup> As in this study, the final clinical results were evaluated by the Denis Pain and Work Scales,<sup>13</sup> in addition to the kyphotic angle by the Cobb method. The mean pain and work score was  $1.5 \pm 0.8$  and  $1.7 \pm 0.9$ , respectively. Segmental kyphosis significantly reduced after surgery, with little loss at the end of follow-up. Regarding the results of the Denis pain questionnaire,<sup>13</sup> it was found that patients answered D1 (no pain), D2 (occasional) and D3 (moderate) scores, characterizing lesser complaints. The results are supported by the studies by Zhao et al. and Liao and Fan.<sup>17,23</sup> When making the same comparison with Denis' work questionnaire scores, a pattern similar to those cited by Liao and Fan was observed, characterizing better ability to return to previous work.<sup>23</sup> When comparing the quality of life results of our operated patients, after 12 months of follow-up, with the results of Laguardia et al., from

the normal population, better results were observed after surgery, suggesting a significant improvement in pain and mobility.<sup>24</sup> This demonstrates the assumption that the surgical procedure described was little disabling from a physical point of view. Finally, this study has some methodological limitations. First, lack of a control group. Second, a greater number of assessments at baseline and postoperatively would allow for a more accurate comparison of patients' functional status and quality of life. Third, the follow-up period of just 12 months. And, finally, the fact that the evaluations were not applied blindly by the evaluator.

## CONCLUSION

Short fixation without arthrodesis and without removal of the implant via the posterior route of A3 and A4 burst-type thoracolumbar spine fractures seems to be an efficient method for spinal stabilization, enabling satisfactory clinical and radiographic results after a minimum follow-up of 12 months.

**AUTHORS' CONTRIBUTION:** Each author contributed individually and significantly to the development of this article. CHTM was responsible for the surgeries performed, study design, collection, interpretation and final preparation of the manuscript. WKN was responsible for data analysis, manuscript preparation and statistical analysis. RM guided all the procedures of this study and approved the final version of the document.







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# AGREEMENT ON MRI DIAGNOSIS IN COMPRESSIVE MALIGNANT VERTEBRAL FRACTURES

## CONCORDÂNCIA NO DIAGNÓSTICO POR RM EM FRATURAS VERTEBRAIS MALIGNAS COMPRESSIVAS

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### ABSTRACT

**Objective:** Verify interobserver and intraobserver agreement of malignant compressive vertebral fractures (MCVF) diagnosis using magnetic resonance imaging (MRI). **Methods:** We retrospectively included a lumbar spine MRI of 63 patients with non-traumatic compressive vertebral fracture diagnoses. Each lumbar vertebra was classified as: without fracture, with fracture of benign characteristics, or with fracture of malignant characteristics. Two medical residents in radiology, one musculoskeletal radiologist fellow, one musculoskeletal radiologist, and two spine surgeons evaluated MRI exams, independently and blindly. Each observer performed two readings, with a 15-day interval between evaluations. A simple Kappa coefficient was used to calculate the intra and interobserver agreement. The reference standard classification was based on bone biopsy or clinical, and imaging follow-up of at least two years, for diagnostic performance analysis. Diagnostic performance was assessed by calculating sensitivity, specificity, accuracy, and positive and negative predictive values with a 95% confidence interval (CI). **Results:** We observed substantial to perfect intraobserver agreement (kappa: 0.80 to 1.00) and substantial interobserver agreement (kappa 0.64 to 0.77). In general, the sensitivity for the detection of MCVF was moderate, except for the second-year radiology resident that achieved a lower sensitivity. The specificity, accuracy, and negative predictive value were high for all observers. **Conclusion:** MCVF diagnosis using MRI showed substantial interobserver agreement. The second-year medical resident achieved lower sensitivity but high specificity for MCVF. Regarding the seniors, there was no statistical significance between spine surgeons and the musculoskeletal radiologist. **Level of Evidence III; Diagnostic.**

**Keywords:** Spinal Fractures, Magnetic Resonance Imaging, Metastasis, Neoplasm, Osteoporotic Fractures, Spine.

### RESUMO

**Objetivo:** Verificar a concordância interobservador e intraobservador no diagnóstico de fraturas vertebrais compressivas malignas (MCVF) por meio de ressonância magnética (MRI). **Métodos:** Incluiu-se retrospectivamente a ressonância magnética da coluna lombar de 63 pacientes com diagnóstico de fratura vertebral compressiva não traumática. Cada vértebra lombar foi classificada da seguinte forma: sem fratura, com fratura de características benignas ou com fratura de características malignas. Dois médicos residentes em radiologia, um pesquisador radiologista musculoesquelético, um radiologista musculoesquelético e dois cirurgiões da coluna vertebral avaliaram os exames de ressonância magnética, independentemente e cegamente. Cada observador realizou duas leituras, com um intervalo de 15 dias entre as avaliações. O coeficiente Kappa simples foi utilizado para calcular o acordo intra e interobservador. A classificação padrão de referência foi baseada em biópsia óssea ou clínica, e acompanhamento por imagem de pelo menos dois anos, para análise de desempenho diagnóstico. O desempenho diagnóstico foi avaliado através do cálculo de sensibilidade, especificidade, precisão, valores preditivos positivos e negativos com um intervalo de confiança de 95% (IC). **Resultados:** Foi observada concordância substancial a perfeita intraobservador (kappa: 0,80 a 1,00) e concordância substancial interobservador (kappa 0,64 a 0,77). Em geral, a sensibilidade para a detecção de MCVF foi moderada, exceto para o segundo ano de residência radiológica que alcançou uma sensibilidade menor. A especificidade, precisão e valor preditivo negativo foram altos para todos os observadores. **Conclusão:** O diagnóstico de MCVF por ressonância magnética mostrou uma concordância substancial entre observadores. O residente médico do segundo ano alcançou uma sensibilidade menor, mas alta especificidade para MCVF. Com relação aos veteranos, não houve significância estatística entre os cirurgiões da coluna vertebral e o radiologista músculo-esquelético. **Nível de Evidência III; Diagnóstico.**

**Descritores:** Fraturas da coluna vertebral, Imageamento por Ressonância Magnética, Metástase Neoplásica, Fraturas por Osteoporose, Coluna Vertebral.

**Citation:** Santos IMG, Herrero CFPS, Pratali RR, Agnollitto PM, Waib FF, Nogueira-Barbosa MH. Agreement on mri diagnosis in compressive malignant vertebral fractures. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 5. Available from URL: <http://www.scielo.br/aob>.

All authors declare no potential conflict of interest related to this article.

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Article received on 12/07/2021, approved in 03/31/2022.



## INTRODUCTION

The occurrence of non-traumatic fractures in the thoracic and lumbar spine segments is a common problem, especially in elderly individuals, with osteoporosis being the leading cause of these fractures.<sup>1,2</sup> On the other hand, the spine is also a frequent site of metastatic disease, which can result in pathological fractures.<sup>3</sup> The etiological diagnosis of these fractures is fundamental since it can modify the therapeutic planning and the prognosis of patients. Failure to diagnose metastatic lesions, or a delay in the diagnosis, may compromise optimal treatment and lead to worse clinical outcomes.<sup>4</sup>

Magnetic resonance imaging (MRI) is considered the gold standard imaging for the differentiation between pathological fractures associated with metastatic lesions and benign osteoporotic fractures.<sup>5-7</sup> Several MRI signs are described as useful in distinguishing between these fractures, but the interpretation of these signs is subjective, and there are no decisive criteria for diagnosis.<sup>5</sup> Thus, accurate diagnosis among such fractures based on imaging examinations, even considering experienced radiologists and spinal surgeons may generate doubts.<sup>4</sup> There is scarce literature on the intraobserver and interobserver agreement in the diagnosis of malignant vertebral compressive fractures (MVCF). To the best of our knowledge, it is not well known whether the medical specialty interferes with the diagnostic performance of MVCF. Thus, the objectives of the present study were to verify intra and interobserver agreement regarding MVCF detection, and to investigate the diagnostic performance of these fractures, comparing radiologists and spine surgeons.

## MATERIALS AND METHODS

### Type of study, population and ethical aspects

This is a retrospective and transverse observational diagnostic study using a database of spine MRI approved by the Institutional Review Board of Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, Brazil (Process HCRP nº 13568/2016). Only patients with a previous diagnosis of compressive vertebral fracture secondary to bone insufficiency or malignant disease were included. The cases were searched using the keywords "fracture", "malignant", "osteoporotic" and "osteoporosis" in the final impression of lumbar spine MRI radiological reports in the Radiological Information System. Exclusion criteria were a history of chemotherapy, radiotherapy, or surgery before the MRI study and previous history of spinal trauma or infection. The MRI files were anonymized and the confidentiality of the patients' identity guaranteed in all the study processes.

A total of 220 patients who had the potential to participate in the study were initially enrolled, but after applying the previously mentioned exclusion criteria, 63 patients were included in the study. Lumbar spine MRI of all patients was acquired on the same equipment (1.5 Tesla, Achieva, Philips, Eindhoven, Netherlands). All patients had their diagnosis confirmed either by a histopathological diagnosis or by a clinical and imaging follow-up for at least two years, in cases in which there was no clinical indication of biopsy.

### Image analysis

Two evaluations of the exams in the DICOM format were carried out by two medical residents in radiology second and third year residents (2ndRR and 3rdRR respectively), one musculoskeletal radiologist fellow (MSKRF), one musculoskeletal radiologist with three years of experience in this area (MSKR) and two spine surgeons. Radiology Medical Residents were at the end of their respective training years. The two spine surgeons with seven and eight years of experience were denominated SS7 and SS8, respectively. The observers performed independent and blind evaluations, without knowledge of the final diagnosis of each patient and data on the

etiology of the vertebral fracture, as well as without information on the other assessments performed by other physicians.

The evaluation was performed with all the images acquired in the clinical routine, with T2-weighted sagittal, axial and coronal images and T1-weighted sagittal plane images. In some cases, additional sequences were used, such as fat saturation sequences and post-contrast MRI sequences. All observers performed the second evaluation of the images, with a minimum interval of two weeks between the assessments, to investigate intraobserver agreement. In the cases of spine surgeons, before the second evaluation, they were exposed to some scientific articles addressing the issue of diagnostic differentiation between benign osteoporotic and malignant fractures,<sup>7,8</sup> and it is possible to verify the diagnostic performance before and after the knowledge deepening in the theme. For the analysis of the interobserver agreement, only the first assessment of all observers was used.

The analysis considered only the five lumbar vertebrae of the patients included in the study. In cases that there were lumbosacral transition vertebrae, these were considered as L5 vertebra to make their identification homogeneous. The lumbar vertebral bodies were numbered from caudal to cranial, and each lumbar vertebral body diagnosed as benign osteoporotic fracture, malignant fracture and absence of fracture.

### Statistical analysis

All analysis was performed with SAS software (SAS Institute Inc., Campus Drive Cary, NC, USA) version 9.0. The intra and interobserver agreement were calculated using the simple Kappa coefficient, calculating the confidence intervals (CI) of 95%. We consider the classification proposed by Landis and Koch<sup>9</sup> in which the Kappa value less than 0.00 is considered poor, between 0 and 0.2 defines slight agreement, between 0.21 and 0.4 fair agreement, between 0.41 and 0.6 moderate agreement, between 0.61 and 0.8 substantial agreement and between 0.81 and 1 almost perfect agreement. Diagnostic performance was defined calculating sensitivity (SEN), specificity (SP), positive predictive value (PPV), negative predictive value (NPV) and accuracy (ACU) in the diagnosis of malignant fractures, with the respective confidence intervals (CI) of 95%.

## RESULTS

### Sample

Of the 63 studied cases, 38 were women and 25 men with a mean age of 62.2 years. Thirty-three cases had a benign osteoporotic fracture (Figures 1 and 2), and 30 patients presented malignant fractures (Figures 3 and 4). Among the malignant fractures, the majority (12 patients, 40%) was due to multiple myeloma, followed by breast carcinoma (8, 26.7%). The other diagnostics were pulmonary carcinoma (1 patient), prostatic carcinoma (2 patients), oropharyngeal carcinoma (2 patients), cholangiocarcinoma (1 patient) paraganglioma (1 patient), miofibroblastic tumor (1 patient) and leukemia (2 patients).

### Intraobserver agreement

The analysis of intraobserver agreement showed almost perfect agreement between the two evaluations performed by almost all observers (Table 1). Only the surgeon with eight years of experience (SS8) presented substantial intraobserver agreement (Kappa = 0.80) and the second-year radiology resident achieved perfect intraobserver agreement (2ndRR) (Kappa = 1.00). There was no statistically significant difference of intraobserver agreement regarding the comparison between the speciality type and degree, except for the 2ndRR. Among the spine surgeons, an intraobserver agreement was higher for the surgeon with seven years of experience (SS7), but with no statistical significance. Comparing the intraobserver agreement between radiologists and surgeons, it was higher for the senior musculoskeletal radiologist.



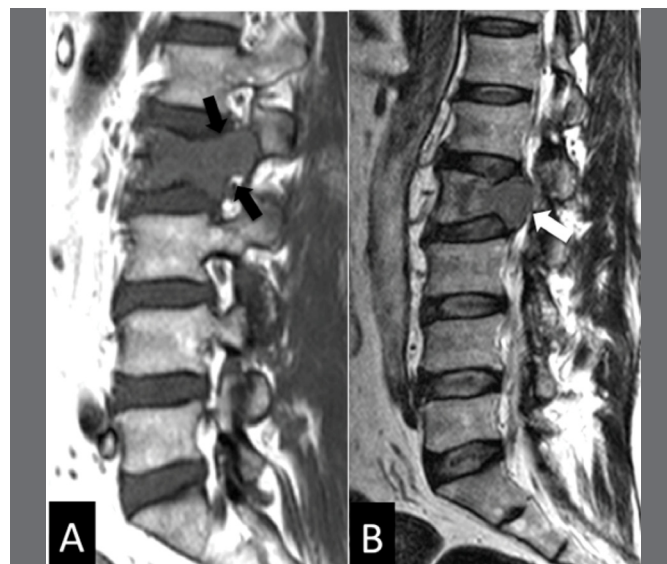
**Figure 1.** Sagittal T1 (A) and T2 (B) MRI, illustrating a case of bone insufficiency fracture of the L1 and L3 vertebral bodies (presence of 4 lumbar vertebrae and 1 lumbosacral transition vertebra). Notice the retropulsion of the posterior wall bone fragment (black arrows) and the preservation of bone marrow signal (white arrows).



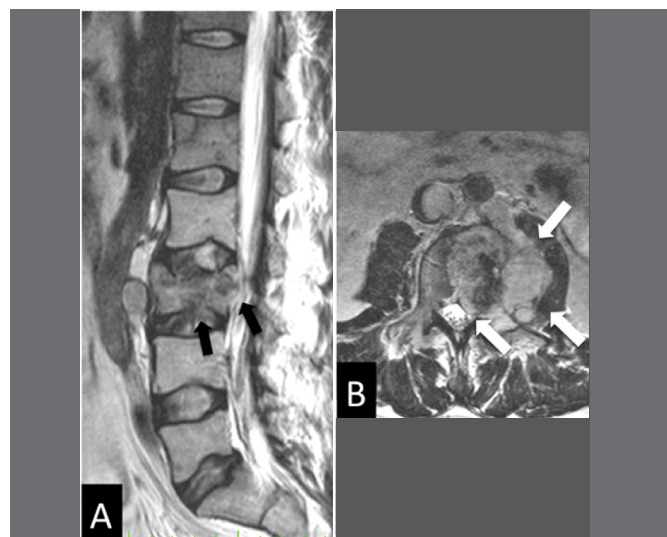
**Figure 2.** Sagittal T1 (A) and T2 (B) MRIs exemplifying a case of bone insufficiency fracture of the L1 and L2 vertebral body. Observe the low signal band in the fracture trace (white arrows) in addition to preserving the bone marrow signal.

### Interobserver Agreement

Interobserver Agreement analysis used the first evaluation of all observers (Table 2). We did not identify a statistically significant difference between the interobserver agreements of different specialties. The interobserver agreement among all observers, considering the confidence intervals, presented results ranging from moderate to almost perfect. Among the radiologists, the highest interobserver agreement was between the 3rdRR and MSKRF with results ranging from substantial to almost perfect. Among the surgeons, the interobserver agreement ranged from moderate to substantial. Among radiologists and surgeons, in general, the interobserver agreement ranged was substantial on (average from 0.62 to 0.77), and the highest agreement occurred between the 3rdRR and SS8 observers.



**Figure 3.** MRI sagittal sequences T1 (A) and T2 (B) exemplifying a case of malignant fracture of the vertebral body of L2. Notice the involvement of the pedicle and the hyposignal throughout the vertebral body (black arrows) and the bulging of the posterior wall (white arrow).



**Figure 4.** Sagittal T2 (A) and axial T2 (B) sequences illustrating a case of malignant fracture of the vertebral body of L3. Observe the low sign of the bone marrow, the bulging of the posterior wall (black arrows), the formation of epidural and paravertebral mass (white arrows).

**Table 1.** Intraobserver agreement, assessed by the simple Kappa coefficient and its respective confidence intervals (95%).

Observer	Agreement coefficient (Kappa)	Confidence intervals (95%)
2ndRR	1.0	1.0 – 1.0
3rdRR	0.82	0.75 – 0.88
MSKRF	0.91	0.87 – 0.95
MSKR	0.97	0.94 – 0.99
SS7	0.90	0.85 – 0.94
SS8	0.80	0.73 – 0.86

2ndRR – second year radiology resident; 3rdRR – third year radiology resident; MSKRF – radiologist fellow; MSKR – radiologist with 3 years of experience; SS7 – spine surgeon with 7 years of experience; SS8 – spine surgeon with 8 years of experience.



## Diagnostic Performance

All values calculated for the evaluation of diagnostic performance are shown in Table 3. Regarding the sensitivity, observers 2ndRR and SS7 presented lower mean values in their first evaluation, but without statistical significance. The SS7 observer showed a significant increase in sensitivity in the second assessment (after the study of the academic articles), still maintaining a mean sensitivity value lower than the other observers, but without statistical significance. The mean values of the sensitivity of the other observers were moderate and similar. The specificity, accuracy and negative predictive value were high for all observers. As shown in Table 3, the PPV ranged from moderate to high values, with no statistically significant difference between the observers.

## DISCUSSION

Despite the importance of accurate diagnosis in spinal fractures between benign osteoporotic and malignant, especially in older individuals, several studies suggest that the determination of specific

criteria for such a differential diagnosis can be difficult.<sup>5,7,10</sup> Nevertheless, the influence of the medical specialty on the performance of this differential diagnosis has not been evaluated. Comparing radiologists with spine surgeons, in addition to the experience of these specialists was the objective of the present study. The intra and interobserver agreement rate were also verified and evaluated according to the medical specialty and professional experience time. In the present study, we did not identify a statistically significant difference in diagnostic performance when distinguishing benign osteoporotic from malignant vertebral fractures between the different training levels. The only exception was the low sensitivity obtained for the second year radiology resident that has been less exposed to MRI training. In general, the specificity (always higher than 90%) was considerably higher than sensitivity in the diagnosis of malignant fractures, so, when evaluated by radiologists and spine surgeons, the observation of signs of malignancy are usually consistent with such diagnosis. Kato et al. also observed specificity higher than 85% in 200 fractures evaluated by two spine surgeons.<sup>7</sup>

In the case of spine surgeons, after reading the academic articles on the subject, we noticed that the acquired knowledge was associated with the improvement in diagnostic performance. Therefore, it was observed that the results are better when there is previous knowledge about the characteristic signs in the imaging examinations of benign osteoporotic or malignant vertebral fractures.<sup>7,8</sup>

Regarding the agreement rate, the rates obtained were classified as being substantial to almost perfect for all observers participating in the study. This would suggest a high reproducibility of the evaluation using the diagnostic characteristics commonly attributed to benign osteoporotic and malignant vertebral fractures. Several authors have reported that the interpretation of the characteristic signs for the differential diagnosis is subjective and, thus, the interobserver reproducibility could be quite variable among the studies.<sup>5,7,11-13</sup>

A striking feature of the present study was that the most frequent diagnostic errors were mainly related to cases diagnosed with multiple myeloma. This greater difficulty for diagnosis in cases of fracture associated with multiple myeloma is in agreement with the literature, being that these fractures frequently present characteristics compatible with benignity in MRI.<sup>14</sup> In the study by Leucovet et al., it was observed that 67% of fractures associated with multiple myeloma had MRI signs characteristic of benign vertebral fractures.<sup>14</sup> Multiple

**Table 2.** Interobserver agreement, assessed by the simple Kappa coefficient and its respective confidence intervals (95%).

	3rdRR	MSKRF	MSKR	SS7	SS8
2ndRR	0.76 (0.69 - 0.83)	0.64 (0.56 - 0.71)	0.64 (0.57 - 0.72)	0.67 (0.6 - 0.74)	0.74 (0.67 - 0.82)
3rdRR		0.77 (0.71 - 0.84)	0.66 (0.59 - 0.73)	0.72 (0.65 - 0.79)	0.77 (0.7 - 0.84)
MSKRF			0.68 (0.61 - 0.76)	0.64 (0.57 - 0.72)	0.65 (0.58 - 0.73)
MSKR				0.62 (0.55 - 0.69)	0.68 (0.6 - 0.75)
SS7					0.67 (0.59 - 0.74)

2ndRR – second year radiology resident; 3rdRR – third year radiology resident; MSKRF – radiologist fellow; MSKR – radiologist with 3 years of experience; SS7 – spine surgeon with 7 years of experience; SS8 – spine surgeon with 8 years of experience.

**Table 3.** Sensitivity (SEN), specificity (ESP), positive predictive value (PPV), negative predictive value (NPV) and accuracy (ACU) analysis, with the respective confidence intervals (CI) of 95%.

	SEN	ESP	PPV	NPV	ACU
2ndRR	36.4 (23.8 - 50.4)	96.5 (93.5 - 98.4)	69.8 (49.2 - 84.7)	87.8 (83.4 - 91.3)	86.1 (82.3 - 89.9)
3rdRR	67.3 (53.3 - 79.3)	96.5 (93.5 - 98.4)	80.4 (66.1 - 90.6)	93.3 (89.6 - 96.0)	91.5 (88.4 - 94.6)
MSKRF	74.5 (61.0 - 85.3)	98.1 (95.6 - 99.4)	89.1 (76.4 - 96.4)	94.8 (91.4 - 97.1)	94.0 (91.4 - 96.6)
MSKR	60.0 (45.9 - 72.9)	96.1 (93.0 - 98.1)	76.7 (61.4 - 88.2)	91.9 (88.0 - 94.9)	89.9 (86.6 - 93.2)
SS7 (E1)	69.1 (55.2 - 80.9)	91.5 (87.5 - 94.6)	63.3 (49.9 - 75.4)	93.3 (89.5 - 96.1)	87.6 (84.0 - 91.2)
SS7 (E2)	70.9 (57.1 - 82.4)	91.5 (87.5 - 94.6)	63.9 (50.6 - 75.8)	93.7 (89.9 - 96.4)	87.9 (84.3 - 91.5)
SS8 (E1)	45.4 (31.9 - 59.4)	94.6 (91.1 - 97.0)	64.1 (47.2 - 78.8)	89.1 (84.8 - 92.5)	86.0 (82.2 - 89.8)
SS8 (E2)	58.2 (44.1 - 71.3)	98.1 (95.6 - 99.4)	86.5 (71.2 - 95.5)	91.7 (87.8 - 94.7)	91.2 (88.1 - 94.3)

2ndRR – second year radiology resident; 3rdRR – third year radiology resident; MSKRF – radiologist fellow; MSKR – radiologist with 3 years of experience; SS7 – spine surgeon with 7 years of experience; SS8 – spine surgeon with 8 years of experience; E1 – first evaluation; E2 – second evaluation.



Myeloma patients comprised 40% of our cases with vertebral fractures secondary to metastasis, and this may explain why average sensitivity achieved for MVCF was just moderate.

Because of the difficulties described here in the differential diagnosis between benign osteoporotic and malignant vertebral fractures, some authors sought to develop instruments that could improve such diagnosis. Recently, a score composed of MRI signs was presented to assist the determination of vertebral fractures by metastases.<sup>7</sup> The authors reported that with the use of the score described by them, they obtained an accuracy rate of 96.6% in the diagnosis of metastatic malignant fractures. In the present study, in which the observers did not use any specific instrument for diagnosis, the mean accuracy was 90.1%, and the musculoskeletal radiology fellow obtained 94% accuracy. In the article in which the META score was described to assist in the diagnosis of MVCF,<sup>7</sup> cases with multiple myeloma were excluded, while in the present study they were included.

More recently, Computed Assisted Classification and Machine-learning techniques have been applied to MVCF diagnosis on spine MRI, with promising results.<sup>15-17</sup> Features derived from Fourier and wavelet transforms, together with the fractal dimension, achieved up to 94.7% of correct classification with the area under the receiver operating characteristic curve (AUC) reaching 0.95.<sup>15</sup> Neural networks achieved AUC of 0.97 in distinguishing between normal and fractured vertebral bodies, and 0.92 in discriminating between benign and malignant fractures.<sup>16</sup> A combination of different classification models composing the ensemble to make the final class assignment reached an average value of AUC = 0.94.<sup>17</sup> Future studies are necessary to confirm artificial intelligence usefulness in the diagnosis of MVCF with external validation.

The present study presents limitations that deserve mention. First, this is a retrospective investigation. Another limitation is that not all cases had histopathological confirmation of the fracture etiology. Cases strongly suggestive of MVCF were biopsied, but in cases that MRI signs favored a benign vertebral fracture, patients were followed clinically and with follow up MRI. All cases had a minimum clinical follow-up of two years from vertebral fracture detection to minimize the risk of including fractures initially identified as osteoporotic fractures but representing a false negative. The classical studies on MVCF also had similar limitation because, in the clinical practice, the biopsy of the vertebral compression fracture is not always necessary or indicated. Therefore, the reference standard for the presence or absence of metastases was based on a best valuable comparator, based on clinical, histologic, biologic, and imaging data.<sup>18-21</sup>

## CONCLUSION

MCVF diagnosis using MRI showed substantial interobserver agreement. The second-year radiology resident achieved lower sensitivity but high specificity for MCVF. Regarding the seniors, there was no statistical significance between spine surgeons and the musculoskeletal radiologist.

## Declarations

Funding: "This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) - Finance Code 001"

Availability of data and material (data transparency): The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

**AUTHORS' CONTRIBUTION:** Each author contributed individually and significantly to the development of this article. IMGS: Material preparation, data collection and analysis, article writing; CFPSH: Material preparation, data collection and analysis, article writing; RRP: Material preparation, data collection and analysis, article writing; PMA: data collection and analysis; TOR: data collection and analysis; FFW: data collection and analysis. MHNb: idea development, article writing and project writing. All authors read and approved the final manuscript.

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# CLINICAL RESULTS OF COLLAGENASE TREATMENT FOR DUPUYTREN'S DISEASE: A CASE SERIES STUDY WITH 2-YEARS FOLLOW-UP

## RESULTADOS CLÍNICOS DO TRATAMENTO COM COLAGENASE PARA A DOENÇA DE DUPUYTREN: UM ESTUDO DE SÉRIE DE CASOS COM 2 ANOS DE ACOMPANHAMENTO

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### ABSTRACT

**Objective:** This study aims to report our experience with *Clostridium Histolyticum* collagenase (CCH) to support the importance of its clinical use and assess its clinical efficacy, complications, and recurrences. **Methods:** This prospective observational study of 66 patients with a 2-year follow-up. Patients with an extension lag major of 20° at the metacarpophalangeal joint (MPJ) and/or proximal interphalangeal joint (PIPJ) were included. We collected data on demographic and anamnestic details, MPJ and PIPJ contracture degrees, DASH score, complications, and recurrences. **Results:** The mean pre-injection contracture was 34° for MPJ and 31° for PIPJ. At the 2-year follow-up, the mean contracture for the MPJ and PIPJ were respectively 3° and 14.5°. The mean DASH score decreased from 21.8 before injection to 10.4 after 2 years. The disease recurrence occurred in 34.8% of the patients, all with PIPJ contracture. The main complication was skin breakage (25.7%). **Conclusion:** The CCH injections remain a consistent option in treating DD; withdrawal from the European market deprives surgeons and patients of low invasiveness and safe tool for treating DD. **Level of evidence IV, Therapeutic study investigating treatment results, Case series.**

**Keywords:** Dupuytren Contracture. Palmar Fibromatosis. Microbial Collagenase. Recurrence.

### RESUMO

**Objetivo:** O objetivo deste estudo é relatar nossa experiência com *Clostridium Histolyticum* collagenase (CCH) para apoiar a importância de seu uso clínico e para avaliar sua eficácia clínica, complicações e recidivas. **Métodos:** Estudo observacional prospectivo de acompanhamento por 2 anos em 66 pacientes com um atraso de extensão maior de 20° na articulação metacarpofalângica (MPJ) e/ou articulação interfalângica proximal (PIPJ). Foram coletados dados sobre detalhes demográficos e anamnéticos, graus de contração da MPJ e PIPJ, escore de DASH, complicações e recidivas. **Resultados:** A média da contração pré-injeção foi de 34° para a MPJ e 31° para a PIPJ. Com 2 anos de acompanhamento, a contração média para a MPJ e PIPJ foi de 3° e 14,5° respectivamente. A pontuação média do DASH diminuiu de 21,8 antes da injeção para 10,4 após 2 anos. A recorrência da doença ocorreu em 34,8% dos pacientes, todos com contração de PIPJ. A principal complicação foi a quebra da pele (25,7%). **Conclusão:** As injeções de CCH continuam sendo uma opção consistente no tratamento do DD; a retirada do medicamento do mercado europeu priva os cirurgiões e pacientes de uma ferramenta pouco invasiva e segura para o tratamento do DD. **Nível de evidência IV, Estudo terapêutico que investiga os resultados do tratamento, série de casos.**

**Descritores:** Contratura de Dupuytren. Fibromatose Palmar. Colagenase Microbiana. Recidiva.

**Citation:** Basso MA, Bernasconi A, Balato G, Cozzolino A, Famiglietti G, Smeraglia F. Clinical results of collagenase treatment for dupuytren's disease: a case series study with 2-years follow-up. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 4. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Dupuytren's disease (DD) is a chronic connective disorder of the palmar fascia of the hand. Usually the disease begins as a palpable nodule and then evolves to form cords with progressive contracture in flexion of the finger.<sup>1</sup> When the fingers flex into the palm, the daily life is severely impaired.<sup>2</sup>

The prevalence of the disease is 0.2% but it can raise up to 50% in some subgroups of patients.<sup>3</sup> Surgical treatments such as open

fasciectomy or needle fasciotomy have always been the gold standard in the treatment of DD, but several complications can occur.<sup>4</sup> In this context enzyme fasciotomy represents an attractive solution, so it has been studied and in the 1996<sup>5</sup> *Clostridium Histolyticum* collagenase (CCH) was tested in vitro, this enzyme had the advantage to be collagen-specific. The first clinical study was published in 2000<sup>6</sup> and in 2010 The Food and Drug Administration approved the collagenase *Clostridium histolyticum* for the

All authors declare no potential conflict of interest related to this article.

The study was conducted at the University of Naples "Federico II", Naples, Italy.

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Article received on 12/16/2021, approved on 07/05/2022.



management of DD. In January 2020 CCH was withdrawn from European Union for commercial reasons.<sup>7</sup> In this context we want to report our clinical experience with CCH to support the importance of the clinical use of this useful drug, which re-defined the gold standard in the treatment of DD.<sup>8</sup>

## MATERIALS AND METHODS

This study is a prospective observational study which started in January 2018. We performed at our institution 66 CCH injections on 66 patients. All the patients expressed written consent. Our institution does not require an ethical approval for observational study. The study is in accordance with Helsinki criteria. The aim of the study is to assess the clinical efficacy of the CCH in the treatment of DD and its complications and recurrences. We included patients with a palpable cord and an extension lag major of 20° at metacarpophalangeal joint (MPJ) and/or proximal interphalangeal joint (PIPJ) were included in the study (Figure 1). We excluded from the study pregnant women, and patient with a Tubiana classification of IV. The injection procedure was performed in outpatient setting. All the injection were performed by a single surgeon (FS) with level 3 experience according to Tang's criteria.<sup>9</sup> After the injection the patients wore a bulky dressing for 3 days. 72 hours from the injection the patient came back to the outpatient clinic and we performed an injection of 5mm of lidocaine. After the onset of the local anaesthetic an extension force was applied on the affected digit to cause the rupture of the cord (Figure 2). The finger was immobilized in extension with a padded Zimmer splint 24 hours for 7 days and later during night for 30 days. We collected the following data before the injection: demographics, Tubiana's stage, MPJ contracture, PIPJ contracture, anamnesis for previous treatments, comorbidities, familiarity, the Disabilities of the Arm, Shoulder and Hand (DASH) score, complications, and recurrences. Complete correction was considered as residual contracture <5°, while recurrence of disease



**Figure 1.** Pre-injection contracture of the V digit.



**Figure 2.** Contracture correction after the rupture of the cord.

was defined as an increase in joint contracture to 20 degrees or more in the presence of a palpable cord at any time during the study.<sup>10</sup> The outcomes were evaluated again at 3 months, 6 months, one year and two years. All the patients were evaluated by a single orthopaedic resident especially trained.

For the statistical analysis, a two-sample *t* test, chi-square test, and Fisher's exact test were used to test the significance of the cross-sectional differences between groups. Pearson's correlation coefficient was used to assess relationships between functional and radiographic out-comes. Age-adjusted univariate and forward stepwise multiple logistic regression analyses were used to determine whether explanatory variables were significantly associated with the recurrence of the pathology. Age-adjusted univariate and multiple forward stepwise linear regression analyses were also used to assess the association of independent variables with the 2 years DASH score. The explanatory variables including in the multivariate analysis were the following: age at operation, sex, Tubiana-stage, multiple cord (categorical: 0 = no; 1 = yes), MPJ contracture (°), number of rays, previous surgery (categorical: 0 = no; 1 = yes), diabetes (categorical: 0 = no; 1 = yes), smoker (categorical: 0 = no; 1 = yes), dialysis (categorical: 0 = no; 1 = yes), familiarity (categorical: 0 = no; 1 = yes), DASH T0, MPJ contracture at 2 years (°), PIPJ contracture (°) at 2 years, recurrence and skin breakage. Before construction of multivariate analysis models, an age-adjusted univariate analysis was performed. All explanatory variables that showed either an association or a trend toward an association (i.e.  $P < 0.10$ ) with the outcome of interest in the univariate analysis were included in our multiple regression models. In the multiple stepwise linear regression analysis, the total  $R^2$  for the model and the changes in  $R^2$  for the independent contribution of single explanatory variables were calculated to assess the percent of total variance in the outcome variable accounted for by the whole model and by single explanatory variables, respectively. A *p*-value of less than 0.005 was considered significant. The SPSS software program (SPSS, Inc., Chicago, IL, USA) was used for the database and statistics.

## RESULTS

From January 2018 through December 2019, we treated 66 consecutive patients with collagenase injections. The mean age of the patients was 64 years (range 33-84) and 57 patients were men (86,3%). Tubiana's stage I was present in 32 patients (48%), Tubiana's stage II in 32 patients (48%), while only 2 patients (3%) had Tubiana's stage III. Demographic and anamnestic details are resumed in Table 1. The mean pre-injection contracture was 34° (range 0°-90°) for MPJ and 31° (range 0°-90°) for PIPJ. At 3 months follow-up, complete correction (residual contracture 0–5°) in treated joints with baseline contracture  $\geq 10^\circ$  was observed in the 86% of MPJ and 26% of PIPJ. At 2-year follow-up, the mean contracture for the MPJ and PIPJ were 3° (range 0-24) and 14,5° (range 0°-60°), respectively. The mean pre-injection DASH score was 21.8 (range 0-80), while the mean DASH score at 2 years was 10,4 (range 0-51). (Table 2).

The recurrence of the disease was observed in 23 patients (34.8%), all with PIP joint contracture. The main complication was skin breakage at time of the finger mobilization that occurred in 17 patients (25.7%), in 1 patient there was no rupture of the cord.

In our model of multiple linear regression analysis, the DASH score at final follow up was directly associated with the pre-injection DASH score ( $c=0.6$ ;  $P<0.001$ ) and the age at the time of injection ( $C=0.3$ ;  $P=0.001$ ). The pre-injection DASH score was by far the most influential predictor in this model, accounting for 71 % in variance of the outcome. The multivariate logistic regression analysis revealed that the pre-injection PIP contracture was the only predictor



**Table 1.** Demographic and Anamnestic details.

<b>Number of patients</b>	<b>66</b>
<b>Gender</b>	
<b>male</b>	<b>57, (86,3%)</b>
female	9 (13,7%)
Mean age, years	64 (range 33-84)
<b>Digit involved</b>	
II	1 (1,5%)
III	7 (10,6%)
IV	23 (34,8%)
V	35 (53%)
<b>Severity (Tubiana's stage)</b>	
I	32 (48%)
II	32 (48%)
III	2 (3%)
<b>Comorbidity</b>	
Diabetes	14
Smokers	18
dialysis	4
Familiarity	13
<b>Previous treatment</b>	
Aponeurectomy	3
Shock waves	1

**Table 2.** Objective and subjective results.

	<b>T0</b>	<b>3m</b>	<b>6m</b>	<b>1y</b>	<b>2y</b>
Mean MPJ contracture (SD)	34,15° (21)	2° (4,3)	2,2 °(4,6)	2,8° (5,4)	3° (5,8)
Mean PIPJ contracture (SD)	31° (29)	10° (11,4)	11,7° (14)	14,6° (17)	14,5° (17)
Mean DASH (SD)	22 (17,3)	13,3 (16,7)	11 (14,6)	11,4 (13)	10,45 (13)

SD= standard deviation

of recurrence of the pathology (odds ratio = 1.1; 95% confidence interval (CI) = 1.05 to 1.1;  $P < 0.001$ ).

At 2-year follow-up, the mean contracture for the MPJ and PIPJ were 3° (range 0-24) and 14,5° (range 0°-60°), respectively. Complete contracture correction, defined as residual contracture 0–5°, was achieved in the 75% of MPJ and in the 26% of the PIPJ.

## DISCUSSION

CCH injections are well supported in literature with positive contracture resolution.<sup>11,12</sup> Our results correspond with the literature; one study<sup>13</sup> of 57 patients reported contracture improvement of the MPJ from 54° to 9° and PIPJ from 30° to 16°, with complete resolution in 80% of MPJ and in 48% of PIPJ. Another study<sup>14</sup> of 87 patients showed improvement from 39° to 14° in MPJ and from 54° to 32° in PIPJ, with a recurrence rate of 28.2% for MPJ and 62.1% for PIPJ. A third study<sup>15</sup> of 77 patients, reported a mean contracture of the MPJ passing from 50° to 17° and of the PIPJ from 44° to 35.5°, with 4 recurrences within the first 6 weeks, and other 12 recurrences at 2-year follow-up (MPJ, 6; PIPJ, 6) reported. In our series, recurrence of the disease, defined as an increased contracture  $>20^\circ$ ,

was observed only in the PIPJ, for a total of 23 patients (34.8%), and, moreover, we found that the only predictor of recurrence of the pathology was the pre-injection PIPJ contracture (odds ratio = 1.1; 95% confidence interval (CI) = 1.05 to 1.1;  $P < 0.001$ ). A higher recurrence rate for the PIP joints, regardless of treatment method, has been also reported by previous studies.<sup>11,12,16</sup> Van Beeck et al.<sup>14</sup> also stated that after the collagenase injection recurrence is more common for the PIPJ. One of the largest studies to assess the long-term efficacy of clostridium injection was the CORDLESS trial, which reported 5-year follow-up data for 623 joints.<sup>11</sup> At 3-year follow-up, the recurrence rates were 16% for MPJ and 38% for PIPJ, while at 5-years follow-up increased to 39% and 66%, respectively. Most of the recurrences (75%) occurred in the first 3 years after treatment. Furthermore, the same authors<sup>11</sup> compared collagenase injection with other techniques of treatment for DD, such as open or needle fasciotomy, and observed similar efficacy in contracture resolution and recurrence with lower complications rates for neurovascular injury and complex regional pain syndrome.

In our series the main complication was skin breakage at time of the finger mobilization that occurred in 17 patients (25.7%), while in 1 patient there was no rupture of the cord. The occurrence of skin tears was recorded in previous studies,<sup>8,17</sup> as well as cord rupture failure.<sup>18</sup> Some studies<sup>18,19</sup> consider skin tears an expected mechanical consequence due to the mechanism of correction rather than a complication, especially for the more severe contractures, demonstrating an increasing risk of a skin tear with increasing contracture severity.<sup>20</sup> Anyway, in our series they all healed quickly without infection, also as previously reported.<sup>17</sup>

We used the DASH questionnaire as subjective outcomes tool and the mean score at the latest follow-up was 10.4. The DASH score at final follow up was directly associated with the pre-injection DASH score ( $c=0.6$ ;  $P < 0.001$ ) and the age at the time of injection ( $C=0.3$ ;  $P=0.001$ ). The pre-injection DASH score was by far the most influential predictor in this model, accounting for 71% in variance of the outcome. Lauritzen et al.<sup>13</sup> observed that the changes in joint contracture and patient satisfaction were associated to the entity of DASH improvement. To date, there is debate about the utility of any patient rated outcome measure for Dupuytren's disease. Even if some authors have tried to validate the DASH questionnaire for Dupuytren's disease, it has not been found to be particularly reflective of clinical changes.<sup>21</sup> In a recent review<sup>8</sup> the authors observed that only few studies used subjective outcome tools and concluded that future studies should concentrate on patient-related outcomes.

The strengths of our study include its prospective design and the use of reliable subjective and objective clinical measurements to assess the outcomes.

The study has some limitations: first the short follow up could underestimate the percentage of recurrence.

## CONCLUSIONS

Serious adverse effects with CCH injections are uncommon and less frequent compared to the rate of major complication occurred after surgical fasciectomy. CCH injection remains a consistent option in the treatment of DD; the withdrawal of the drug from European market deprives surgeons and patients of a low invasiveness and safety tool which has changed the treatment of DD.

**AUTHORS' CONTRIBUTION:** Each author made significant individual contributions to the development of this manuscript. BMA: acquisition, analysis and interpretation of the study data and writing of the work; BA: substantial contribution to the design of the work and critical review of its intellectual content; BG: final approval of the version of the manuscript to be published; CA: substantial contribution to the design of the work and critical review of its intellectual content; FG: acquisition, analysis and interpretation of the study data; SF: writing the work and performing surgery.



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# PROSPECTIVE CONTROLLED STUDY OF SPINAL SURGERY VERSUS PHYSICAL CAPACITY

## ESTUDO PROSPECTIVO CONTROLADO DA CIRURGIA VERTEBRAL VERSUS CAPACIDADE FÍSICA

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### ABSTRACT

**Objective:** Assess whether the spine surgical approach for degenerative diseases can influence the physical capacity of patients and its correlation with cardiorespiratory function. **Methods:** A prospective study was conducted on 9 patients of both genders, aged between eighteen and sixty, scheduled for spinal surgery for degenerative disease in the lumbar segment. Patients underwent treadmill stress test two times, fifteen days before and sixty days after the surgery. A cardiologist performed the test according to the Bruce protocol with a progressive increase in incline and speed. **Results:** There were no statistically significant differences between pre- and postoperative assessments for the parameters evaluated in the treadmill stress test. Forty-four percent of patients needed to interrupt the test postoperatively due to dyspnea ( $p=0.023$ ). **Conclusion:** The improvement obtained with spinal surgery does not have statistically significant relevance in tiredness, pain, and fatigue in the lower limbs and low back pain. Some patients could not complete the examination after surgery due to poor physical conditioning, and it was necessary to interrupt the examination due to dyspnea. **Level of Evidence II; Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization).**

**Keywords:** Orthopedic Surgery. Osteoarthritis. Spine. Exercise Test.

### RESUMO

**Objetivo:** Avaliar se a abordagem cirúrgica da coluna vertebral para doenças degenerativas pode influenciar a capacidade física dos pacientes e sua correlação com a função cardiorrespiratória. **Métodos:** Um estudo prospectivo foi realizado em 9 pacientes, de ambos os sexos, com idade entre 18 e 60 anos, programados para cirurgia de coluna vertebral para doenças degenerativas no segmento lombar. Os pacientes foram submetidos a teste de esforço em esteira duas vezes, quinze dias antes do procedimento cirúrgico e sessenta dias após a cirurgia. O teste foi realizado por um cardiologista de acordo com o protocolo Bruce com aumento progressivo de inclinação e velocidade. **Resultados:** Não houve diferenças estatisticamente significativas entre as avaliações pré e pós-operatórias para os parâmetros avaliados no teste de esforço em esteira. Quarenta e quatro por cento dos pacientes precisaram interromper o teste no pós-operatório devido à dispnéia ( $p=0,023$ ). **Conclusão:** A melhora obtida com a cirurgia da coluna vertebral não apresenta impactos estatísticos no cansaço, dor e fadiga relativos aos membros inferiores e dores lombares baixas. Alguns pacientes não puderam completar o exame após a cirurgia devido ao mau condicionamento físico, exigindo a interrupção do exame devido à dispnéia. **Nível de Evidência II; ECRC de menor qualidade (por exemplo, < 80% de acompanhamento, sem mascaramento do código de randomização ou randomização inadequada).**

**Descritores:** Cirurgia Ortopédica. Osteoartrite da Coluna Vertebral. Teste de Esforço.

**Citation:** Almeida VCPA, Felix HF, Navarro FAM, Salles AF, Oliveira CN, Rodrigues LCL. Prospective controlled study of spinal surgery versus physical capacity. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 3. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

The search for chronic low back pain treatment is growing.<sup>1</sup> Low back pain is considered chronic if lasts longer than six months. It is estimated that 70 to 85% of the world's population will experience back pain at some point in their lives.<sup>2</sup> In Brazil about ten million of Brazilians suffer with disabilities caused by low back pain,<sup>3</sup> which is

considered a public health problem.<sup>4</sup> LBP can be caused by several factors, such as inflammation, muscle weakness and degenerative diseases. Disc degeneration is related to environmental effects, injuries caused by trauma, smoking, atherosclerosis and the natural aging.<sup>5</sup> The lumbar spine is divided according to its functional capacity; in anterior, middle, and posterior. The anterior portion of spine

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Departamento de Ortopedia e Traumatologia do Hospital Santa Marcelina, São Paulo, SP, Brazil.

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Article received on 09/10/2021, approved in 02/18/2022.



is made up of the intervertebral discs and vertebral bodies. The middle portion consists of the spinal canal and pedicles. The posterior portion is responsible for directing the functional units in the movements of anterior/lateral flexion, extension and rotation.<sup>6</sup> The intervertebral disc works as a hydraulic system, absorbing shock and distributing the load evenly.<sup>7</sup> Thus, the amount of water in its composition it is proportional to its absorption capacity.<sup>8</sup> Intervertebral disc collagen production occurs in three phases: the initial one, where there is abundant collagen production; the maturation phase, which maintains collagen renewal; and, finally, the degenerative phase, where there is a decrease in renewal.<sup>9</sup> As it is an avascular structure, the nutrition of the disc occurs by diffusion.<sup>10</sup> Anatomically described, the soluble regulators of cell function indicate the aging and senescence of the disc - which consists of a nucleus pulposus surrounded by an annulus fibrosus. The nucleus pulposus acts allows the vertebral disc to withstand forces of compression and torsion, permitting the liquid exchange between capillaries and vertebral discs and the axis of vertical movement between two vertebrae. The fibrous annulus, on the other hand, participates in the stabilization and movement of the vertebral bodies and loads dampening.<sup>11</sup> However, with aging, its biomechanical efficiency starts to decrease due to dehydration.<sup>12,13</sup> The nucleus pulposus progressively loses its capacity to hold water and the annulus fibrosus begins to lose its elasticity, demonstrating the degradation of the nutrition mechanism and then resulting in disc degeneration.<sup>14</sup> New studies show that the main factors influencing healthy and degenerated intervertebral disc are: mechanical load, genetic influences, diffusion of nutrients and oxygen through the intervertebral disc matrix.<sup>14</sup>

The treatment of chronic low back pain, among its many causes, includes several therapeutic options, from conservative treatment to surgical intervention.<sup>6</sup> In this study, we sought to assess the physical capacity of patients undergoing surgical treatment of the spine through the treadmill stress test. In addition to diagnosing cardiovascular diseases, the treadmill stress test also determines prognosis and assesses therapeutic responses to exercise tolerance, in addition to being a test considered to be of low risk. The patient is submitted to a programmed physical effort, which allows the assessment of their clinical, electrocardiographic, hemodynamic, metabolic, autonomic and ventilatory responses. The test will enable the evaluation of the therapeutic interventions results and the patient's actual physical conditions.<sup>15</sup>

The aim of this study was to assess whether the spine surgical approach for degenerative diseases can influence the physical capacity of patients, correlating it with cardiorespiratory function.

## METHODS

This study was approved by the research ethics committee and (number 2.904.787/2018) was carried out in accordance with the 1995 Declaration of Helsinki in the period from May 2019 to May 2020. Nine patients of both genders, aged between eighteen and sixty years, scheduled for spinal surgery for degenerative disease in the lumbar segment were included. Patients with neuromuscular diseases, history of cardiovascular diseases, spine fractures, any sequelae on spine, pelvis and lower limbs diseases were excluded due to limitations in performing the treadmill stress test.

A prospective study was carried out, with qualitative and quantitative data collection. Patients were submitted to the exercise test in two moments, which would be done fifteen days before the surgical procedure and sixty days after the surgery.

The test was performed by a cardiologist according to the Bruce protocol with a progressive increment in inclination and speed, to assess functional capacity.<sup>9</sup> For this purpose, a treadmill was

used for thirty minutes, and vital signs such as blood pressure, respiratory and heart rate were measured.

Data collection began after approval by the Research Ethics Committee and the signing of the free and informed consent form by the volunteers.

A significance level of 0.05 (5%) was defined for this work. We chose to use non-parametric tests, as the dataset has a low sampling. Pre and post operative tests were compared using the Wilcoxon test, as the data are paired.

## RESULTS

Nine patients were included, 6 females and 3 males. The minimum age was 18 years and the maximum age was 62 years with an average of 45 years.

All patients included had the degenerative condition of the lumbar spine as their underlying disease, and all underwent spinal arthrodesis with instrumentation of up to 3 levels.

When evaluating the associated comorbidities, we considered as obesity patients those with a body mass index (BMI) above 35 and overweight BMI ranging from 28 to 34.9. The distribution of comorbidities was presented in Table 1, remember that comorbidities may overlap, because patients may have more than one associated disease. The results of the pre and postoperative test evaluation are presented in Table 2. There were no statistically significant differences between pre and postoperative assessments for the parameters evaluated in the treadmill stress test.

When we analyzed the reason for the interruption of the test (Table 3), we observed a statistically significant difference ( $p = 0.023$ ) in one of the reasons for interruption. Forty four percent of the patients needed to interrupt the postoperative test due to dyspnea that not observed in the preoperative evaluation.

## DISCUSSION

This study evaluated the surgical approach in the treatment of degenerative disease of the spine, with a treadmill stress test performed in the preoperative and postoperative periods (3-month). The mean age of patients was 44.6 years, with a low variability, keeping the data homogeneous and in accordance with the previous literature.<sup>16,17,18</sup> There was no difference regarding gender distribution, even with the prevalence of female with 66.7% and male with 33.3% ( $p$ -value 0.157). This prevalence of female gender was found in several literature review papers for chronic low back pain.<sup>19</sup>

The obesity was the most recurrent comorbidity in this study, with 44.4%, and it may be one of the variables with the most interference in the postoperative evaluation. Patients had an increase in body weight, which may be due to improved pain, mood, and reduced use of oral medications, which could lead to an improvement in gastrointestinal feelings. In several papers, obesity has been listed as an important factor in etiology and pain. One of these studies was carried out with an epidemiological profile of Brazil.<sup>19</sup>

In the comparison pre and postoperative for the treadmill stress tests, our aim was to evaluate the patient's physiological changes after the surgery improvement in the low back pain and the limitation

**Table 1.** Comorbidities distribution.

Comorbidities	N(%)
Obesity	4(44,4)
Smoker	2(22,2)
Ex-smoker	3(33,3)
Arterial hypertension	2(22,2)
Overweight	2(22,2)
Dyslipidemia	1(11,1)

**Table 2.** Comparison between pre and postoperative for treadmill stress testing.

	Moments	Mean	Median	Standard deviation	Minimum	Maximum	IC	P-value
Weight (kg)	Pre-Operative	72.1	66	15.6	46	95	10.2	0.513
	Post-Operative	72.8	69	14.7	47	99.4	9.6	
Speed (mph)	Pre-Operative	3.29	3.40	0.52	2.50	4.20	0.34	0.196
	Post-Operative	2.83	3.40	1.29	1.20	4.20	0.84	
Distance (miles)	Pre-Operative	0.299	0.300	0.124	0.110	0.460	0.081	0.374
	Post-Operative	0.261	0.230	0.201	0.010	0.520	0.131	
Interruption time (m:sec)	Pre-Operative	07:40	07:38	02:41	03:30	11:59	01:45	0.214
	Post-Operative	06:14	06:16	04:09	00:30	10:59	02:43	

**Table 3.** Comparison between the different reasons for interruption of the exam.

Reasons for interruption	Pre-Operative N (%)	Post-Operative N(%)	P-value
Tiredness	2(22.2)	1(11.1)	0,527
Pain in lower limbs	5(55.6)	4(44.4)	0,637
Fatigue in the lower limbs	1(11.1)	0(0.0)	0,303
Low back pain	1(11.1)	0(0.0)	0,303
Dyspnea	0(0.0)	4(44.4)	0,023 *

\* statistically significant p value.

it could be causing. However, it was not significant between these two moments. No previous similar study was found in literature. The moments (pre- and postoperative) and the reasons of treadmill stress test interruption were evaluated. It was found that there is a statistical difference between the moments for the distribution of dyspnea, where the percentage raised from 0.0% in the preoperative period ( $p = 0.023$ ) to more than 44% in the postoperative period, which led us to think that even with the improvement in pain and functional limitation, obesity may influence the dyspnea, since even some patients being smokers or former smokers, they did not present preoperative dyspnea. We did not find papers to make a comparison with the data obtained in our study. This study presents us with some questions and directs us to new variables to be observed in the surgical treatment of the spine, emphasizing the importance of metabolic disorders and obesity, for example, not only as triggering factors, but also as harmful factors in the intra and postoperative.

Relevant information was given to patients, such as problems encountered in the postoperative period. Aiming to improve clinical conditions and quality of life, trained multidisciplinary professionals such as nutritionists, psychologists and physiotherapists were suggested. We can also think that dyspnea may not have been observed, as the mechanical disorder of chronic low back pain would not allow this patient to make great efforts, which may not allow an activity that would cause dyspnea. The removal of this factor associated with the time of postoperative convalescence could add another factor not analyzed. Perhaps the need for earlier and more intense rehabilitation after surgery, after removing the mechanical factor, could be the best option to improve this limiting clinical condition. Some limitations of our study must be presented – small sample and short follow-up – however, it could provide us with new possibilities for study, leading to future research.

## CONCLUSION

Improvement achieved with spinal surgery does not have a statistically significant in tiredness, pain, and fatigue in the lower limbs in patients with chronic low back pain.

Regarding patients who were not able to complete the treadmill stress test due to physical limitations after surgery, this probably occur due to poor physical conditioning, being necessary to interrupt the test due to dyspnea.

## ACKNOWLEDGMENTS

To the Cardiology Department of Hospital Santa Marcelina for their support.

**AUTHORS' CONTRIBUTION:** VCPAA: critical review of intellectual content, conception, acquisition, analysis, data interpretation, writing and final approval. HFF: critical review of intellectual content, writing and final approval. FAMN: critical review of intellectual content, conception and final approval. AFS: critical review of intellectual content, conception and final approval. CNO: critical review of intellectual content, conception, and final approval. LCLR: critical review of intellectual content, design, analysis, data interpretation, writing and final approval.

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# COST ANALYSIS OF MOTORCYCLE ACCIDENT VICTIMS AT A UNIVERSITY HOSPITAL: PERSPECTIVES FROM 2017 AND 2020

## ANÁLISE DE CUSTO DAS VÍTIMAS DE ACIDENTE MOTOCICLISTICO EM UM HOSPITAL UNIVERSITÁRIO: PERSPECTIVAS DE 2017 E 2020

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### ABSTRACT

**Introduction:** Motorcycle accidents constitute a public health problem that affects public and private health services due to the expenses of the victim's treatment and rehabilitation. **Objective:** Evaluate the impact of motorcycle accident costs in a university hospital in 2020. **Method:** Comparative analysis of the costs of motorcycle accident patients in 2020 and 2017. **Results:** Among 151 patients included in the study, the average cost was U\$3,083.54, and the average days of hospitalization were 5.3 days. The patient with the highest cost to the hospital spent U\$22,504.05, and the patient with the lowest cost spent U\$356.72. The longest stay among these patients was 41 days, and the shortest was one day. The average cost per patient per day for the entire sample was U\$581.80. **Conclusion:** The formulation and application of strategies that promote the reduction of motorcycle accidents in the city of Campinas are necessary. **Level of evidence II, Retrospective study.**

**Keywords:** Accidents, Traffic, Hospitalization, Costs and Cost Analysis.

### RESUMO

**Introdução:** Acidentes motociclisticos constituem um problema de saúde pública que atinge os serviços públicos e privados de saúde, em função dos gastos com o tratamento e com o processo de reabilitação da vítima. **Objetivo:** Avaliar o impacto dos custos dos acidentes motociclisticos em um hospital universitário em 2020. **Método:** Análise comparativa dos custos dos pacientes vítimas de acidente motociclistico no ano de 2020 e 2017. **Resultados:** Dentre 151 pacientes incluídos no estudo, o custo médio foi de U\$3.083,54 e a média de dias de internação foi de 5,3 dias. O paciente que apresentou maior custo para o hospital, teve um gasto de U\$22.504,05 e o que teve o menor custo, gastou U\$356,72. O maior tempo de internação, entre estes pacientes, foi de 41 dias e o menor tempo foi de 1 dia. O custo médio por paciente por dia, em toda a amostra, foi de U\$581,80. **Conclusão:** Faz-se necessário a formulação e aplicação de estratégias que promovam a redução dos acidentes motociclisticos na cidade de Campinas. **Nível de evidência II; Estudo retrospectivo.**

**Descritores:** Acidentes de trânsito, Hospitalização, Custos e Análise de Custo.

**Citation:** Baptistella A, Figueiredo HCS, Mattos CA, Bittar CK. Cost analysis of motorcycle accident victims at a University Hospital: perspectives from 2017 and 2020. *Acta Ortop Bras.* [online]. 2023;31(1)Esp.: Page 1 of 4. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Traffic accidents have had an important impact on the health of populations in several countries around the world. According to the World Health Organization, around 1.24 million people die each year due to traffic accidents, and it is the leading cause of death among young people aged 15 to 29 years.<sup>1,2</sup> Brazil, in recent decades, has gradually been ranked among the world champions in traffic accidents, with emphasis on accidents involving motorcycles. This vehicle has increasingly gained acceptance and approval from the population.<sup>3</sup> The COVID-19 pandemic had dramatic consequences for the health system organization. Although orthopedics and traumatology, as medical specialties, do not deal directly with the effects caused by

SARS-CoV-2, its performance was significantly affected, especially at Hospital PUC-Campinas, due to its qualification as a reference for the care of traumas and "non-covid" pathologies.<sup>4,5</sup> The study of direct cost in health aims to quantify, in monetary values, how much resources were used directly in the treatment/intervention of a patient and can be subdivided into medical (fees, hospitalization, medication, etc.) and non-medical (transportation) costs patient, feeding, etc.). Indirect costs refer to the loss of working time of the patient or their families due to the disease or its treatment, which can be measured, for example, in terms of lost productivity.<sup>6</sup> Therefore, the dimension of costs is quite broad, and only a portion of them was addressed here. Furthermore, the present study analyzed only direct medical expenses related to hospital

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Department of Orthopedics and Traumatology of Hospital PUC-Campinas.

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Article received on 11/23/2021, approved on 01/28/2022.



admissions. The time interval for analysis is restricted to one year, and the examination of data relating to a single university hospital is another limitation.

The present study aimed to describe and compare hospitalization rates for motorcycle accidents at a university hospital in 2020, estimate the direct medical cost and length of stay of hospitalizations for motorcycle accidents.

## METHODS

That is a cross-sectional, descriptive, comparative, and retrospective study, with a quantitative approach, based on the cost reports of patients victims of motorcycle accidents conducted between January/2020 and December/2020, as it aims to observe, record, and analyze the costs of Hospital PUC-Campinas with this group. The Research Ethics Committee filed this study with registration on Plataforma Brasil under number 88812818.30000. We waived the patient consent because we retrospectively analyzed previously collected anonymous data; the Research Ethics Committee approved the use of data for these purposes.

All patients victims of motorcycle accidents hospitalized for those 12 months at the Hospital PUC-Campinas, located in Campinas, covering the entire Northwest region of the city, were included. The institution also received cases from other areas of Campinas because it qualified as a reference to caring for the flow of "non-covid" traumas and pathologies.<sup>5</sup>

We defined a victim of a motorcycle accident upon entering the service at Hospital PUC-Campinas. We identified the patients from the emergency Surgery and Trauma Service team - SCUT of the hospital.

We obtained the information on hospital costs for each patient from our hospital cost accounting database. The cost per patient method was applied, considering the value of the hospital rate, procedures, direct product, third party, fee, and days of hospitalization. We included a comparison of the cost between patients victims of motorcycle accidents in 2020 and patients in 2017, using data collected by the "Socioeconomic impact of motorcycle accident victims in the emergency room of a hospital (Part 2)".<sup>7</sup> Values were adjusted for inflation, understood as when the same nominal amount of money buys less in terms of a fixed basket of goods and services.<sup>8</sup> Thus, costs were first inflated using the National Consumer Cost Index (IPCA) (Table 1). Values were then converted from the local currency (R\$) to US\$, using the exchange rate relative to the period during which the cost data was collected (Table 2).

With this data in hand, we calculated using simple arithmetic the average cost of each patient and the average number of days of hospitalization. According to the trauma mechanism, the average cost of patients and the average number of days of hospitalization for these groups. It was also possible to calculate the average patient/day cost by comparing the average cost and the average number of days of hospitalization. Categorical variables were presented as absolute frequencies and percentages.

**Table 1.** Basic correction data by IPCA (IBGE).

Data reported	
Initial date	01/2017
Final date	12/2020
Final value	R\$ 1,00 (REAL)
Calculated data	
Correction index in the period	1,16434630
Corresponding percentage value	16,434630 %
Value corrected on the end date	R\$ 1,16 (REAL)

## RESULTS

We included 150 patients during the study period. Table 3 shows the most frequent admissions among patients involved in a collision with automobiles (53.6%).

Among the 151 patients, the average cost was US\$ 3,083.54 (US\$ 356.72 - 22,504.05), and the average hospital stay was 5.3 days (1 - 41 days). Thus, the average cost per patient per day across the entire sample was \$581.80.

Likewise, compared to 2017, the average cost was U\$8,708.77 per patient, and the average hospital stay was 13 (1 - 87 days). The patient with the highest cost had an expense of U\$70,689.65 and the lowest, U\$972.10. Therefore, the average cost per patient per day was \$669.90.

In the present study, for the 81 patients victims of a motorcycle versus car collision (53.6%), there was an average cost of U\$ 3,018.27 (U\$ 366.74 - 22,488.21). Furthermore, the average length of stay was 5.2 (1 - 41 days), and the average cost was US\$580.43 per patient/day.

Among the 40 patients who were victims of motorcycle falls (26.5%), there was an average of 4.5 days of hospitalization (1 - 34 days). The average cost was U\$2,786.00 (U\$356.72 - 22,196.24), and the average per patient/day was U\$619.11.

For the 16 patients victims of a motorcycle versus fixed object collision (10.6%), there was an average cost of U\$ 4,482.51 (U\$ 948.61 - 14,183.89). The average length of stay was 7.3 (1 - 25 days), and the average cost was U\$129.94 per patient/day.

Of the total 14 patients in the sample, victims of less frequent trauma mechanisms (motorcycle versus motorcycle, motorcycle versus bicycle, and motorcycle versus animal), there was an average of 6.3 days of hospitalization (1 - 17). Therefore, the average cost was US\$3,250.78 (US\$1,049.33 - 7465.2), and the average per patient/day was US\$515.99.

**Table 2.** Monthly Average Commercial Dollar Quotation (US\$) for Sale in Real (R\$).

Months	2017	2020
January	3,197	4,152
February	3,103	4,346
March	3,127	4,894
April	3,140	5,330
May	3,209	5,640
June	3,297	5,203
July	3,205	5,287
August	3,153	5,459
September	3,138	5,403
October	3,196	5,632
November	3,257	5,422
December	3,297	5,142

**Table 3.** Trauma mechanism of patients victims of motorcycles accidents in a university hospital, 2020.

Trauma mechanism	n	%
Motorcycle versus car	81	53,6
Motorcycle crash	40	26,5
Motorcycle versus fixed object	16	10,6
Motorcycle versus motorcycle	6	4,0
Motorcycle versus bicycle	5	3,3
Bike versus animal	3	2,0

The total value of hospital admissions of patients victims of motorcycle accidents, from January 2020 to December 2020, analyzed in this study, totaled US\$ 465,614.82.

## DISCUSSION

The emergency care and traumatology drained a large part of the financial resources of the health sector for the rehabilitation and social inclusion of victims of traffic accidents.<sup>9</sup> Thus, traffic accidents affect around 1 to 2% of the domestic product (GDP) of low- and middle-income countries, which corresponds to a cost of over 100 billion dollars a year.<sup>10</sup>

In the present study, the 151 admissions for motorcycle-related accidents at the Hospital PUC-Campinas, in 2020 generated a total cost of US\$465,614.82 and an average cost of US\$3,083.54 per hospitalization in 2020. Differed from that of the average value per admission found in the study "Socioeconomic impact of motorcycle accident victims in the emergency room of a hospital (Part 2)"<sup>6</sup> for the same hospital in 2017, with 62 admissions, which was R\$ 8,708.77; proving a reduction of 64.5% in costs. Furthermore, there was also a difference concerning the mean length of stay. In the current study, the mean length of stay was 5.5 days, while, in the study mentioned above, it was 13 days.

The increase in the number of hospitalizations is possibly related to the pandemic situation and the expanding market for delivery and motorcycle taxis. According to Diniz et al., the reality of these professionals (motorcycle courier and "motorcycle taxi driver") surpasses the emotion of riding a motorcycle. Precarious conditions, lack of formal contracts, long hours, stress, psychological pressure for greater productivity, low income, and risks of accidents are constant. The motorcycle courier live with the risk-need dialectic, reported by Veronese & Oliveira: "Between working under the threat of suffering a traffic accident and not working, what to choose? It is up to the motorcycle courier to try to control the risk".<sup>11</sup>

Furthermore, the central role of Hospital PUC-Campinas in taking care of trauma cases may also be linked to the substantial increase in the number of cases.

Regarding the length of stay, we expected that the incidence of COVID-19 in these patients would increase the span of hospital stay, either by aggravating the patient's clinical condition and prolonging

his recovery or by the need to comply with quarantine requirements during the period of hospitalization.<sup>12</sup> Furthermore, it is plausible that the surgery of patients diagnosed with COVID-19 was postponed, influencing postoperative recovery and possibly contributing to the increase in hospital stay, as shown in other studies.<sup>13-15</sup>

However, as demonstrated above, the reduction in a hospital stay can probably be justified by the recommendations on preparing perioperative environments to support the immediate care of patients with general emergency surgery and traumatized in times of COVID-19 and avoid delays. Moreover, surgical interventions are not limited to patients who are victims of motorcycle accidents.

The "Guia rápido para a atuação dos coordenadores de serviços de Trauma no Brasil", for example, is general guidelines developed by the Brazilian College of Surgeons (CBC), the Brazilian Society for Integrated Trauma Care (SBAIT), and the Brazilian Chapter of American College of Surgeons, based on those provided by the American College of Surgeons and its Committee on Trauma.<sup>16</sup> Likewise, these measures and recommendations, together with the reduced length of stay, may justify the reduction in the average cost per patient.

According to the present study, motorcyclists were predominantly victims of a motorcycle versus car collision, representing 53.6%, followed by motorcycle falls (26.5%) and motorcycle versus fixed object collision (10.6%). Thus, the trauma mechanism is essential for predicting injuries, which makes them more suspicious, and, through early diagnosis and treatment, it can often offer the patient a better prognosis.

As a limitation of the present study, it is highlighted that the data refer only to hospitalizations financed by Hospital PUC-Campinas. Therefore, the results presented represent the reality of only one institution.

## CONCLUSION

The data on hospitalization costs arising from accidents involving motorcycles at the Hospital PUC-Campinas, in 2020 only reinforces the need to formulate and apply strategies that promote the reduction of motorcycle accidents in Campinas. We hope that similar studies will provide the basis for adopting prevention policies and improving the care provided to these victims.

**AUTHORS' CONTRIBUTION:** Each author contributed individually and significantly to the development of this article. AB: data analysis, statistical analysis, article writing. HCSF: data analysis, revising it critically for important intellectual content, final approval of the version to be published. CAM: data analysis, revising it critically for important intellectual content, final approval of the version to be published. CKB: data analysis, revising it critically for important intellectual content, final approval of the version to be published.

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# EFFICACY AND SAFETY OF KNOTLESS BARBED SUTURES IN CAPSULAR CLOSURE FOLLOWING DISTAL FEMUR FRACTURE FIXATION

## EFICÁCIA E SEGURANÇA DAS SUTURAS FARPADAS SEM NÓS NO FECHAMENTO CAPSULAR APÓS FIXAÇÃO DE FRATURA DISTAL DO FÊMUR

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### ABSTRACT

**Introduction:** Good wound closure is an important step in management of distal femur fracture to prevent infection and faster rehabilitation. Knotless barbed sutures can save time and distribute wound tension evenly. However, its role in terms of functional outcome, closure time, and postoperative complications has not been studied in a distal femur fracture. **Material and methods:** A total of 47 patients aged more than 18 years of distal femur fracture treated with distal femur locking plate were randomized either into either barbed or traditional suture groups. In the barbed group, capsular wound closure was carried out with 2-0 bidirectional barbed knotless sutures (Quill SRS® PDO, Angiotech, Vancouver, BC, Canada). In patients assigned to group B, capsular closure was done with 1-0 Vicryl® (Ethicon inc. Somerville, NJ) and 5-0 Ethibond® alternatively. **Results:** The mean flexion at the knee joint was  $105.7 \pm 15.6$  degrees in the study group while it was  $110.4 \pm 13.7$  in the control group ( $p = 0.2133$ ). Mean estimated closure time was significantly shorter in the study group as compared to the control group ( $p < 0.05$ ). Cases of needle prick injury were higher in traditional suture group. Patients developed stitch abscess and superficial infection in both groups. However, the difference in incidence between the two was not statistically significant. **Conclusion:** Barbed suture is an efficient method of wound closure. It reduces wound closure time with similar complication rate as with use of conventional sutures. **Evidence Level II; Randomized Clinical Trial.**

**Keywords:** Surgical Procedure, Suture Techniques, Femur, Femoral Fractures.

### RESUMO

**Introdução:** O fechamento adequado da ferida é um passo importante no manejo da fratura distal do fêmur a fim de evitar infecção e permitir uma rápida reabilitação. Suturas farpadas sem nós podem poupar tempo e distribuir uniformemente a tensão da ferida. Entretanto, seu papel em termos de resultado funcional, tempo de fechamento e complicações pós-operatórias não tem sido analisado em casos de fratura distal do fêmur. **Material e métodos:** Um total de 47 pacientes com mais de 18 anos de idade com fratura distal do fêmur tratados com placa de fixação distal do fêmur foram aleatorizados em grupos de sutura farpada ou tradicional. No grupo de farpados, o fechamento da ferida capsular foi feito com suturas sem nós farpadas bidirecionais 2-0 (Quill SRS® PDO, Angiotech, Vancouver, BC, Canadá). Em pacientes designados para o grupo B, o fechamento capsular foi feito com Vicryl® 1-0 (Ethicon inc. Somerville, NJ) e Ethibond® 5-0 respectivamente. **Resultados:** A flexão média na articulação do joelho foi de  $105,7 \pm 15,6$  graus no grupo de estudo e  $110,4 \pm 13,7$  no grupo controle ( $p = 0,2133$ ). O tempo médio estimado de fechamento foi significativamente menor no grupo de estudo em comparação com o grupo controle ( $p < 0,05$ ). Os casos de ferimento por perfuração da agulha foram maiores no grupo de sutura tradicional. Os pacientes desenvolveram abscesso de pontos e infecção superficial em ambos os grupos. Entretanto, a diferença na incidência entre os dois não foi estatisticamente significativa. **Conclusão:** A sutura farpada é um método eficiente para o fechamento de feridas. Ele reduz o tempo de fechamento das feridas com uma taxa de complicação semelhante à utilização de suturas convencionais. **Evidência Nível II; Ensaio Clínico Randomizado.**

**Descritores:** Procedimento Cirúrgico, Técnicas de Sutura, Fêmur, Fraturas Femorais.

**Citation:** Lakhani A, Khatri K, Malhotra N, Banga RK, Bansal D. Efficacy and safety of knotless barbed sutures in capsular closure following distal femur fracture fixation. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 5. Available from URL: <http://www.scielo.br/aob>.

All authors declare no potential conflict of interest related to this article.

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Article received on 03/28/2021, approved in 06/24/2022.



## INTRODUCTION

The incidence of distal femoral fracture is approximately 10 per 100,000 with bimodal age distribution.<sup>1</sup> Despite continued improvements in the implants used for fixation of distal femur fractures, stiffness is one the most commonly encountered problem. Stiffness results from delayed mobilization at the knee joint following fracture fixation in the majority of cases.<sup>2,3</sup> With the invent of newer distal femur locking plates active mobilization at knee joint is possible in the immediate postoperative period. However, there are other factors like closure of arthrotomy wound and suture material used which could determine the end results. Traditionally, arthrotomy closure with simple interrupted sutures and multiple knots results in uneven tension and is also time consuming. From this perspective, knotless sutures allow multiple simultaneous bidirectional knots distributing tension evenly across the entire length of arthrotomy and also saves valuable time.

Barbed sutures are being used in urogynaecological procedures, general surgery and plastic surgery.<sup>4-6</sup> However, there is debate over the safety profile of knotless barbed sutures across the spectrum. Majority of the studies carried out till date evaluated for closure time, functional outcome and complications in arthroplasty procedures.<sup>7-9</sup> To the best of our knowledge, no study to date had evaluated complication rate and functional outcome of capsular closure carried out with barbed knotless sutures in distal femur fracture fixation. The aim of study was to determine if barbed sutures offer any advantage over conventional sutures in case of arthrotomy closure following distal femur fracture fixation. We hypothesized that use of barbed knotless sutures would result in 1) shorter wound closure time 2) similar complication rates 3) better clinical outcomes in comparison to traditional knotted sutures as early mobilization could be initiated at the knee joint.

## MATERIAL AND METHODS

The current study is a randomised controlled trial comparing two different techniques of wound closure (barbed knotless versus standard knotted sutures) in cases of distal femur fracture treated with locking compression plate. The approval for this study was obtained from the institutional review board. The consent was taken from the patients prior to surgery.

Patients included in the study were cases of distal femur fracture (AO type 33 A, B, C1 and C2) treated with single distal femur locking plate operated through lateral parapatellar approach. Complex distal femur fracture AO type 33C3 were not included in the study as they would require sometimes dual plating or medial parapatellar approach for management of fracture. Patients with Gustilo Anderson type 2 and 3 compound injuries, multiple injuries, head injury, subjects below the age of 18 years and patients with uncontrolled diabetes mellitus were also excluded from study.

The study was powered to calculate the number of participants necessary to detect a difference of five minutes between two suture groups from previous studies conducted in use of barbed sutures.<sup>8</sup> With an alpha of 0.05 and a power of 80%, we expected the findings to be significant if the number of subjects was 47.

Patients were randomly assigned to receive closure using barbed knotless sutures (Group A) or standard conventional sutures (Group B). Randomisation process was performed with the closed envelope system just before starting the closure process. Previous to the study, all the participants went through training with application of barbed knotless sutures in not less than 10 cases. Participants were not informed of their allocation during the trial but they could request for the information at the end of study. Surgeons and supporting staff were not blinded. Though radiographs were reviewed by independent assessors still due to presence of implants they were not blinded.

Subjects were reviewed in daily trauma meet and operated on next available theatre. Each patient received a single intravenous dose of cefuroxime preoperatively one hour prior to surgery and two intravenous doses postoperatively. Preparation, fracture reduction and other intraoperative decisions were left to the discretion of the operating surgeon. The distal femur fractures were approached through lateral parapatellar knee arthrotomy. All fractures were fixed with the help of distal femur locking compression plate (Nebula Surgical, Rajkot, India) plate. All surgeries were performed in an inpatient setting with variable length of stay depending upon pain and functional ambulatory status of the patient.

In patients assigned to group A, capsular wound closure was carried out with 2-0 bidirectional barbed knotless sutures (Quill SRS® PDO, Angiotech, Vancouver, BC, Canada). Barbs are arranged in a helical fashion around the suture radiating in both directions.<sup>10</sup> They created a tension in the opposing direction when passed through tissue working towards ends starting at the midpoint of wound. The operating surgeon worked towards one end while the assistant proceeded towards the other end. At the ends, the suture direction was reversed and again approached towards the midpoint. After engaging a few throws, the suture ends were cut without knot tying. In patients assigned to group B, capsular closure was done with 1-0 Vicryl® (Ethicon inc. Somerville, NJ) and 5-0 Ethibond® alternatively. The skin and subcutaneous tissue were closed with the help of skin staplers and Vicryl 2-0 respectively in both groups. The capsular closure was carried out by the operating surgeon while skin and subcutaneous closure was completed by the assistant. The total closure time i.e. period of commencement of first stitch to skin closure was registered in both groups with the help of a stopwatch. The stopwatch was stopped in case of suture breakage and resumed once the new suture pack was opened again.

Non-adherent primapore dressing was applied over the wound. Dressing was changed on the second postoperative day and subsequently after every three days till suture removal at 14th postoperative day.

The in-bed mobilisation of the patients was started on the first postoperative day. They were advised to bend the knee as per pain tolerance. Toe touch and partial weight bearing was advised as per progress of fracture healing and stability. Full weight bearing was allowed between 9 to 12 weeks upon fracture union.

Preoperative data was collected on a standard form at the time of admission. Operative parameters included were start time of wound closure, completion of wound closure, total number of sutures used and any other intraoperative complication. Wound infection was graded based on the scale described by Hollander et al<sup>11</sup> It was graded as no infection, simple stitch abscess, cellulitis, accompanying lymphangitis and systemic symptoms.

The functional outcome was evaluated using EQ-5D-5L<sup>12</sup> EQ-5D-5L is a health utility instrument to measure quality of life across five domains namely mobility, self-care, usual activities, pain and depression. It was assessed after operative procedure, at the end of 6 weeks and 12 weeks. Radiographs were evaluated on the second postoperative day, at six weeks and at 12 weeks. Loss of fixation, varus or valgus deformity of greater than 5 degrees, shortening of more than one centimetre, recurvatum/procurvatum >10 degree were recorded.

## Statistical analysis

Demographic technical and risk factors were compared between both the groups to detect the confounding effects. Means with standard deviation were reported for all continuous variables and compared using independent 2-tailed t tests. Categorical variables were reported as frequencies per population and compared by chi-square analysis. Fisher's exact test was used when in groups

with five or fewer subjects. Spearman's correlation coefficient was used to determine if there was association between different variables in the study group. The p-value for describing statistical significance was set at  $<0.05$ .

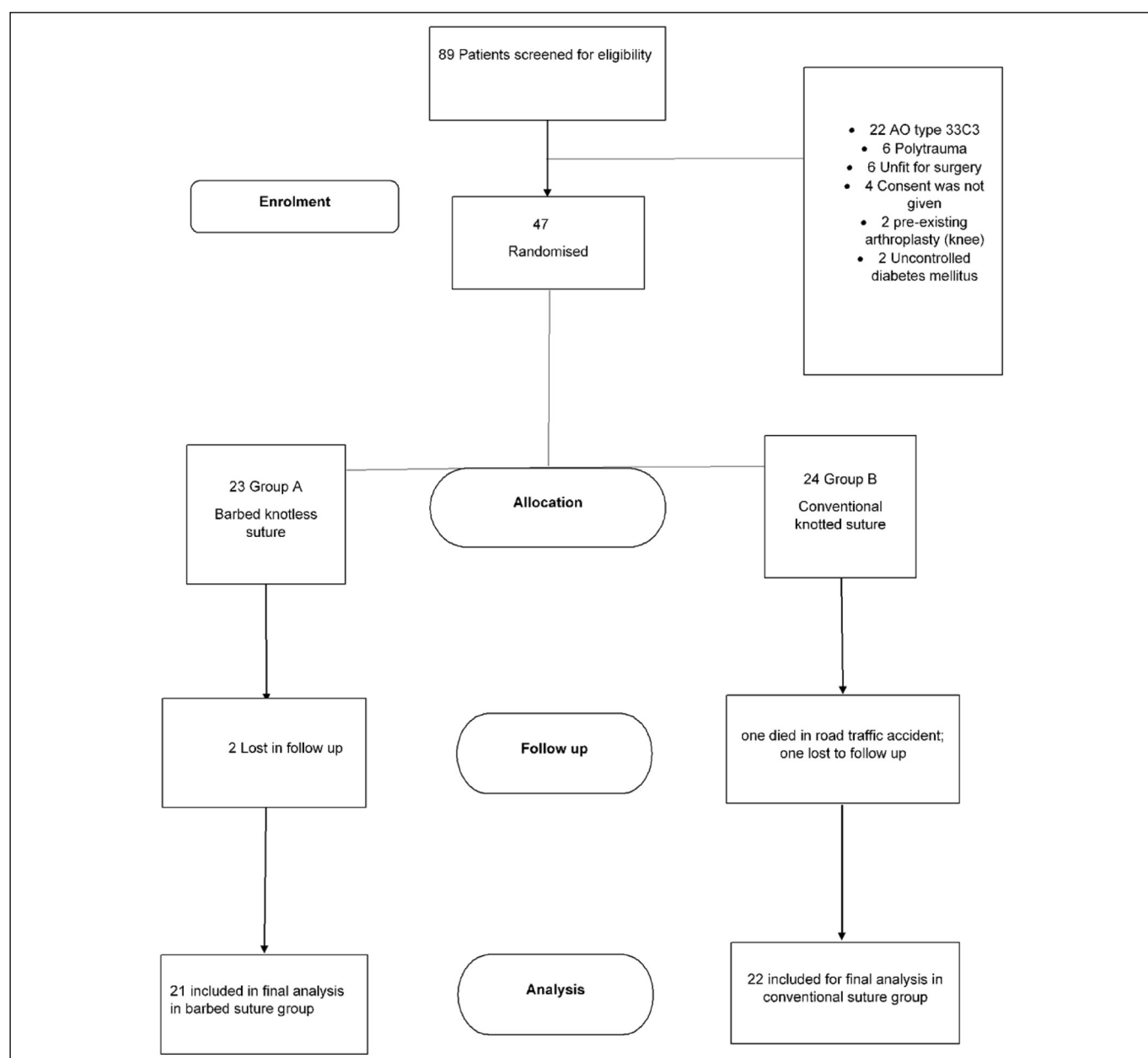
## RESULTS

Patients were recruited between September 2014 and November 2020. Of the 89 patients screened, the most common reason for not inclusion of subjects in study was AO type C3 of distal femur fracture. (Figure 1) 47 participants were randomised into the trial. The study group consisted of 23 cases while the knotted/control group comprised 24 cases. There were 14 females (29.78%) and 33 males (70.21%). Patient characteristics including age, gender, body mass index and smoking status were recorded (Table 1). Mean estimated closure time was significantly shorter in the study group as compared to the control group ( $p<0.05$ ). The incidence of suture breakage was significantly higher in the group using barbed

knotless sutures for wound closure ( $p=0.02$ ). The surgical staff had reported no case of needle stick injury in the barbed suture group while three cases were reported in the conventional suture group. The difference was not statistically significant ( $p=0.08$ ). (Table 2) The mean flexion at the knee joint was  $105.7\pm15.6$  degrees in the study group while it was  $110.4\pm13.7$  in the control group ( $p=0.2133$ ). The difference was not clinically significant. Among the 47 subjects, EQ-5D-5L questionnaire was completed by 41 (87%, 95%CI 65% to 97%), 30 (65%, 95%CI 43% to 83%) and 29 (61%, 95%CI 39% to 80%) patients at the baseline, 6 weeks and 12 weeks. The data collected was insufficient to achieve any meaningful conclusion between the groups. (Table 3)

## Wound complications

Patients developed stitch abscess, superficial infection and lymphangitis in both groups. However, the difference in incidence between the two was not statistically significant. (Table 4) One patient in the barbed suture group had developed deep seated



**Figure 1.** Consolidated standards of reporting trials (consort) flow diagram.

**Table 1.** Patient Demographics.

Variable	Barbed suture group (n=23)	Knotted suture group (n=24)	P value
Age (years)	43.2 8.7	41.2 6.7	0.3807
Gender			
Male	17 (74%)	16 (67%)	
Female	6 (26%)	8 (33%)	
Body Mass Index (kg/m <sup>2</sup> )	20.4 7.3	22.3 5.6	0.3209
Smoker	3 (13%)	2 (8%)	0.5794
Controlled Diabetes	4 (17%)	2 (8%)	0.3546
Mechanism of injury			
Road Traffic Accident	18 (78%)	16 (67%)	
Fall while walking	5 (22%)	8 (33%)	
Time interval from admission to surgery (days)	5 2.4	6 2.7	0.1870
Fracture Classification (AO/OTA)			
A1	7 (30.4%)	6 (25%)	
A2	2 (8.7)	2 (8.3%)	
B1	1 (4.3%)	2 (8.3%)	
B3	0 (0%)	1 (4.1%)	
C1	8 (34.7%)	7 (29.1%)	
C2	5 (21.7%)	4 (16.7%)	

**Table 2.** Outcome by type of suture.

Variable	Barbed suture group (n=23)	Conventional suture group (n=24)	P value
Wound closure time (in minutes)	11.5 3.4	17.3 4.5	< 0.0001
Suture breakage	5 (20.8%)	0	0.02
Needle prick	0	3 (12.5%)	0.083

**Table 3.** Patient reported outcome measured through EQ-5D-5L health questionnaire.

Time frame	Barbed suture group (n=23)	Conventional suture group (n=24)
Post injury	-0.04 (0.26; 11)*	-0.05 (0.25; 10)
6 weeks	0.35 (0.32; 9)	0.19 (0.17; 7)
12 weeks	0.40 (0.37; 8)	0.36 (0.31; 9)

\* Indicates mean; standard deviation.

**Table 4.** Wound complications.

Variable	Barbed suture Group (n=23)	Conventional suture group (n=24)	P value
Stitch abscess	4 1.8	3 1.9	0.0708
Cellulitis	3 1.1	3 1.3	1
Sepsis with systemic symptoms	1 0.5	0	>0.99
Lymphangitis	1 0.5	1 0.5	1

infection and was subjected to irrigation and debridement. Intravenous antibiotics (injection piperacillin with tazobactam) for six weeks followed by oral antibiotic therapy (tablet cefuroxime) were administered. There was no recurrence at the time of last follow up (one and half years).

Cellulitis was analysed to assess for association between dermal closure ( $r = -0.03$ , 95% CI -0.14 to 0.09), smoking ( $r = 0.01$ , 95% CI -0.08 to 0.11), age ( $r = 0.02$ , 95% CI -0.09 to 0.12) and BMI ( $r = -0.06$ , 95% CI -0.05 to 0.17), none of were found to be correlate at six weeks.

Subsequently, two tailed post hoc analysis was carried out to determine the number of distal femur fractures required to get a statistically significant difference in cellulitis and incidence of needle stick injury (power at 0.8 and  $\alpha = 0.05$ ). It was calculated that the number of subjects in each group required to detect any statistically significant result would be 418,321 for cellulitis and 819 for needle stick injury. So, it is likely that no clinically significant between the two group exists.

## DISCUSSION

Good wound closure is critical to minimize wound related complications.<sup>13</sup>

The principle finding of the current study is that barbed knotless sutures significantly reduce the closure time following fixation of distal femur fracture when compared with conventional sutures. Another finding of the study was that the complication rates were similar in both groups and do not depend upon the type of suture material used.

Wound closure was faster in a barbed knotless suture group and similar findings were noted in other studies though conducted in arthroplasty patients. Chan et al<sup>10</sup> reported an average reduction of 4 minutes in closure time whereas Gilliland et al<sup>14</sup> noted a reduction of 4.6 minutes in overall closure time. Such minor reduction in surgical time needed for closure of an arthrotomy wound does not have any repercussions on the long-term results.

Interrupted knotted sutures have traditionally been used in closure of arthrotomy wounds following fixation of distal femur fractures. The conventional interrupted sutures have few disadvantages. Handling of needle during knot tying puts surgeons at an additional risk of injury. Interrupted sutures put uneven pressure along the length of wound which might lead to tissue ischemia resulting in necrosis in some cases and resultant tissue could be a source of infection. Knotless barbed sutures however had several advantages like equal distribution of tension across the length of wound and minimal risk to surgeons due to lesser knot tying. The wound healing related complications were not significantly different in two groups. There was also no major difference in satisfaction scores. Range of motion at the knee joint, especially flexion showed no difference between barbed knotless sutures and traditional sutures. The similar finding was noted by Chan et al.<sup>10</sup> We had expected better results with barbed knotless suture because running suture share out mechanical forces in a better way. However, there are many other factors which affect the range of movement at the knee joint.

It is also worthwhile to note that the barbed sutures resist failure to a greater extent as compared to conventional sutures. In case of suture rupture, the anchoring barbs hold the suture in a place. Vakil et al<sup>15</sup> in their study on cadaveric knees used barbed sutures for closure of arthrotomy wounds and subjected to repeated cycling. It was concluded that the arthrotomies closed with barbed sutures resisted failure in comparison to conventional sutures. However, there are higher chances of suture breakage as encountered in our study. There were five cases of suture breakage in the barbed group in comparison to the control group and the difference was statistically significant ( $p=0.02$ ).

Morris et al<sup>16</sup> suggested that barbed monofilament sutures were associated with decreased bacterial adhesion in comparison to conventional suture. This should hence protect against infection. However, Campbell et al<sup>17</sup> and Chawla et al<sup>18</sup> reported higher incidence of infection with use of barbed sutures. In our study there was no difference between the barbed suture and conventional suture application. There were limitations to our study. First, with a limited number of subjects we could not ascertain if there is statistically significant difference between groups in rates of wound related complications and needle stick injuries. However, with the large group and post hoc analysis, clinically significant difference in wound related complications could not be ascertained. Second, many confounding



variables like obesity and comorbid conditions could be excluded before randomization which may have an effect on final outcome. Third, the study involved cases of distal femur fracture and hence the findings of the same cannot be extrapolated for its use in other orthopaedic procedures.

In conclusion, use of barbed sutures is associated with shorter closure time, a higher chance of suture breakage and similar functional outcome. There were similar wound-related closure complications in comparison to conventional closure of arthrotomy wounds after distal femur plating.

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**AUTHORS' CONTRIBUTION:** Each author contributed individually and significantly to the development of this article. AL: Writing of the article, editing and Interpreting data ; KK: Writing of the article, interpreting data and approval of the manuscript; NM: Literature search, writing of manuscript; RKB: interpreting data and approval of the manuscript; RM: Data interpretation and final approval of the version of the manuscript to be published; DB: performing surgeries, interpreting data and approval of the manuscript.

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# RELATION OF FEMUR FRACTURES LOCATION WITH CLINICAL OUTCOMES IN ELDERLY PATIENTS

## RELAÇÃO DA LOCALIZAÇÃO DAS FRATURAS DE FÊMUR COM DESFECHOS CLÍNICOS EM PACIENTES IDOSOS

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### ABSTRACT

**Objective:** This study was designed to investigate the possible relationship between the anatomical location of the PFF (head-neck fractures) and the demographic features, comorbidities, and risk factors of elderly patients. **Methods:** 233 patients aged 65 years and over, who were admitted to the emergency department with a diagnosis of proximal femur fracture were included in this study. **Results:** Most patients (59.6%) had a trochanteric fracture. The incidence of trochanteric fractures had a statistically significant positive correlation with age. Falls at ground level were found to be highly associated with trochanteric fractures (92.8%). At least one complication was observed in 57 (41.0%) cases and 31 (22.3%) died in one year, of the patients with trochanteric fractures. Comorbidity was not related to fracture location statistically. Fall ground level ( $p = 0.013$ ), complication rate (73.7%;  $p < 0.001$ ), and Charleson comorbidity index ( $p = 0.019$ ) were statistically significantly associated with death. The logistic regression analysis of variables determined that only the quantity of comorbidities may be related to femoral neck fractures ( $p = 0.047$ ). **Conclusion:** Female patients with trochanteric fractures were found to be older than male patients. Fall ground level, mortality, and complications were more frequently seen in patients with trochanteric fractures. **Level of Evidence II, Retrospective study.**

**Keywords:** Femoral Fracture, Incidence, Aged, Mortality, Emergency Medical Services.

### RESUMO

**Objetivo:** Este estudo foi desenhado para investigar a possível relação entre a localização anatômica da PFP (fraturas de cabeça e pescoço) e as características demográficas, comorbidades e fatores de risco de pacientes idosos. **Métodos:** Foram incluídos 233 pacientes com idade igual ou superior a 65 anos, admitidos no pronto-socorro com diagnóstico de fratura do fêmur proximal. **Resultados:** A maioria dos pacientes (59,6%) apresentou fratura trocantérica. A incidência de fraturas trocaterianas apresentou correlação positiva estatisticamente significativa com a idade. Verificou-se que as quedas no nível do solo estão altamente associadas às fraturas trocatericas (92,8%). Pelo menos uma complicação foi observada em 57 (41%) casos e 31 (22,3%) morreram em um ano, dos pacientes com fraturas trocatericas. A comorbidade não foi realizada estatisticamente com a localização da fratura. Queda do nível do solo ( $p = 0,013$ ), taxa de complicações (73,7%;  $p < 0,001$ ), índice de comorbidade charleson ( $p = 0,019$ ) foram estatisticamente significativamente associados à morte. Na análise de regressão logística das variáveis, determinou-se que apenas a quantidade de comorbidades pode estar relacionada às fraturas do colo do fêmur ( $p = 0,047$ ). **Conclusão:** Pacientes do sexo feminino com fraturas trocatericas foram consideradas mais velhas do que pacientes do sexo masculino. Queda no nível do solo, mortalidade e complicações foram observadas com mais frequência em pacientes com fraturas trocatericas. **Nível de evidência II, Estudo retrospectivo.**

**Descritores:** Fratura Femoral, Incidência, Idoso, Mortalidade, Servicios Médicos de Urgencia.

**Citation:** Celik B, Kose A, Milcan A, Yarkac A, Babus SB, Erdogan S. Relation of femur fractures location with clinical outcomes in elderly patients. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 5. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Proximal femoral fractures (PFF) are a frequent cause of admission to the emergency department (ED), particularly in elderly patients and are associated with higher mortality, morbidity, and healthcare costs than any other osteoporotic fractures.<sup>1,2</sup> About 250,000 hip fractures

occur annually in the United States (US) and it is expected to increase over the coming years, due to the aging population. The mortality rate in patients with PFF in the US is 7% within a month and 24% within a year.<sup>3</sup> PFFs are an important economical burden for healthcare. Medical treatment for injuries cost around 8.68 billion dollars.<sup>4</sup>

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Mersin University Hospital, Emergency Medicine Department.  
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Article received on 06/23/2020, approved in 11/06/2020.



The known risk factors for PFF are; old age, female gender, sedentary lifestyle, alcohol and tobacco consumption, benzodiazepines, anticonvulsant drugs, cerebrovascular events, diabetes, osteoporosis, hyperthyroidism and some other chronic diseases.<sup>5</sup> Besides that, some morbidities and mortality may develop after PFF. Therefore, it is important to assess comorbidities, potential risk factors, and monitor patients closely for prospective complications.<sup>6,7</sup>

Even a low-energy trauma (like a simple fall) may result in PFF. Approximately 30% of people aged 65 and over fall once a year.<sup>8,9</sup> Many researchers have considered hip fractures as a single, homogeneous condition. Based on their anatomical locations, there are two main types of PFF: Trochanteric fractures and head-neck fractures. The potential risk factors affecting the type of fractures were investigated only in a few studies.<sup>2,5</sup> Our study aims are to analyze the possible predisposing factors for the type of PFF and the prognoses of the patients. Several studies suggested that the type of fractures and their outcomes may be associated with some factors addressing the need for new studies.<sup>2,5,10</sup> The type of PFF may affect mortality as well. Nevertheless, very few details were found on patients with proximal femur fractures who applied to the ED.

This study aimed to investigate a potential association between risk factors, comorbidities, socio-demographic and clinical features, and the type of PFF (trochanteric fractures and head-neck femur fractures) in patients presenting aged 65 years and over.

## MATERIAL AND METHOD

### Study Design

After the approval from the ethical board (dated 26.04.2018 and numbered 2018/188) patients aged 65 and over who were admitted to a University Hospital ED with a diagnosis of PFF between 01.01.2016-30.04.2018 were included in this study. As a result, 233 patients aged 65 and over who met the inclusion were included in the study. Our study was conducted by scanning the data of the patients according to the ICD-10 diagnostic codes via Nucleus, the hospital electronic information operating system, and confirmed with radiographs. All data were analyzed retrospectively. A descriptive cross-sectional study was conducted. Before the study, approval was received from the Clinical Research Ethics Committee dated 26.04.2018 and numbered 2018/188.

### Parameters of the Study

First, the location of PFF was classified as trochanteric or head/neck. Intertrochanteric fractures, major and minor trochanteric fractures, and unspecified fractures in this region, were included in the group of trochanteric fractures. Intracapsular, femoral neck, femoral head, sub-capital, and unspecified fractures in this region, were recorded as femoral neck fractures.

Age, gender, mechanism of injury, comorbidities, Charlson Comorbidity Index (CCI), concomitant injuries, the American Society of Anesthesiologists (ASA) score, length of hospitalization, time to surgery, complications, causes of death were evaluated in these patients.

The patients were classified in three groups by their age as 65-74, 75-84, and more than 84. Comorbidities were assessed according to the CCI and classified as mild in the presence of 0-2 comorbidities, moderate into the presence of 3-4 comorbidity, and serious in the presence of 5 and more comorbidities. Time-to-surgery was reported in 24 hour-intervals for each patient. According to the ASA scores, ASA 1 was described as mild risk, ASA 2 as moderate risk, ASA 3 as high risk, and ASA 4 as very high risk. Deaths due to all causes occurring within 1 year were recorded.

Patients with incomplete data, under 65 years of age, patients without proximal femur fractures, were not included in the study.

### Statistical analysis

The Shapiro-Wilk test was used to determine if the continuous variables were normally distributed. Mann Whitney U test was used for differences between some parameters according to the location of the fracture. The Student t-test was used for the differences between the average ages. Mann Whitney U test was used for differences between continuous measurements according to primary and secondary causes of death. Average and standard deviation values are given for those with normal distribution in descriptive statistics. For those who do not have a normal distribution, minimum, maximum, median, 25-75% percentages are given. Pearson's chi-square and Likelihood ratio chi-square tests were used for categorical variables. Logistic regression analysis was applied in terms of some parameters according to the fracture type and survival status. Statistical significance was taken as  $p < 0.05$ .

## RESULTS

Between the dates of 01.01.2016-30.04.2018, 233 patients over 65 years of age with PFF were admitted to ED, Trochanteric fracture was found in 59.7% ( $n = 139$ ) of these patients, and neck fracture in 40.3% ( $n = 94$ ) (Figure 1). 149 of the patients were women and 84 men.

The mean age of patients with trochanteric fracture ( $82,03 \pm 7,0$ ) was higher than the patients with neck fracture ( $79,62 \pm 7,8$ ) ( $p = 0.015$ ). Majority of patients (%83,4) aged 75 years and over were diagnosed with trochanteric fracture ( $p = 0.049$ ). (Table 1) The majority of PFFs were found to be fall ground level ( $n = 220, 94.4\%$ ) ( $p = 0.178$ ). There was no accompanying injury in 91% ( $n = 212$ ) of PFFs. 79% ( $n = 184$ ) of patients were operated. HT was present in 45.9% ( $n = 107$ ) of patients, DM in 35.2% ( $n = 82$ ) of the patients whereas and total %87,5 of them had at least one comorbidity.

No statistically significant difference was found between trauma mechanism, accompanying injury, surgical condition, fracture location, ASA score, length of stay, comorbid index, comorbidity status, number of comorbidities, time to surgery, and fracture side ( $p > 0.05$ ). Complication rate was 34.8% ( $n = 81$ ). Patients with trochanteric fractures had statistically significantly more complication rates (%41) than patients with neck fractures (%25,5) ( $p = 0.015$ ). (Table 1) It was determined that 16.3% of the patients with PFF died within 1 a year. The mortality rate after one year of follow-up was significantly higher in patients with trochanteric fractures than neck fractures, which were %22,3 and %7,4 respectively ( $p = 0.003$ ). (Table 1)

In the logistic regression analysis of variables affecting the fracture type, only the number of comorbid was determined to be effective on the fracture type. Accordingly, it was determined that the comorbid number of trochanteric fractures is lower than femoral neck fractures ( $p = 0.047$ ). (Table 2)

There was no statistically significant correlation between the mortality and the gender, age, side of the fracture, time-to-surgery of the patient. (Table 3) However, It has been found that mortality is associated with fall ground level ( $p = 0.013$ ), complication development ( $p < 0.001$ ), comorbid index ( $p = 0.015$ ), high ASA score ( $p = 0.001$ ), length of stay ( $< 7$  days) ( $p = 0.017$ ). (Table 3) The difference between the number of comorbidities was found to be significant in patients who survived after 1 year ( $p = 0.008$ ). Although the median values are equal, the mean rank values of those who died (mean rank = 142.75) were significantly higher than those who lived (Mean rank = 111.98).

## DISCUSSION

Several studies have been conducted on PFFs concerning diagnosis, treatment, and survival according to the fracture location, and various results have been achieved. In the study of Endo et al. in

**Table 1.** Demographic and clinical features of the patients by fracture site.

Parameters	All patients (n=233)	Neck (n=94, 40.3%)	Trochanteric (n=139, 59.7%)	P
Age (Mean SD)	81,06 7,4	79,62 7,8	82,03 7,0	0,015
<b>Age groups</b>				<b>0,049</b>
65-74 age	50 (21.5)	27 (28.7)	23 (16,5)	
75-84 age	97 (41.6)	39 (41,5)	58 (41,7)	
≥85 age	86 (36.9)	28 (29,8)	58 (41,7)	
Gender, Women	149(63.9)	61 (% 64,9)	88 (63,3)	0,805
<b>Trauma mechanism</b>				<b>0,178</b>
Fall from height	4 (1.7)	0 (0,0)	4 (2,9)	
NVTA	7 (3.0)	3 (3,2)	4 (2,9)	
IVTA	2 (0.9)	0 (0,0)	2 (1,4)	
Fall ground level	220 (94.4)	91 (96,8)	129 (92,8)	
Accompanying injury	21 (9.0)	7 (7,4)	14 (10,1)	0,492
Mortality	38 (16.3)	7 (7,4)	31 (22,3)	0,003
Complication	81 (34.8)	24 (25,5)	57(41,0)	0,015
Fracture side, Left	130 (55.8)	53 (56,4)	77 (55,4)	0,882
Fracture side , Right	103(44.2)	41 (43,6)	62 (44,6)	
Surgical condition	184 (79.0)	79 (84,0)	105 (75,5)	0,118
<b>ASA Score</b>				<b>0,670</b>
Moderate	39 (20.4)	19 (23,5)	20 (18,2)	
High	83 (43.5)	34 (42,0)	49(44,5)	
Highest	69 (36.1)	28 (34,6)	41 (37,3)	
<b>Length of stay</b>				<b>0,696</b>
<7 days	161 (69.0)	64 (80,0)	97 (82,2)	
>7 days	37 (15.8)	16 (20,0)	21 (17,8)	
Mild comorbidity index	135 (57.9)	52 (55,3)	83 (59,7)	0,596
Moderate comorbidity index	54 (23.1)	25 (26,6)	29 (20,9)	0,393
Severe comorbidity index	15 (6.4)	7 (7,4)	8 (5,8)	0,829
Comorbidity	204 (87.5)	84 (89,4)	120 (86,3)	0,492
<b>Comorbidities</b>				
DM	82 (35,2)	33 (35,1)	49 (35,3)	0,982
HT	107 (45,9)	47 (50,0)	60 (43,2)	0,304
Alzheimer/demens	52 (22,3)	23 (24,5)	29 (20,9)	0,517
Parkinson's disease	14 (6,0)	8 (8,5)	6 (4,3)	0,186
Cerebrovascular disease	15 (6,4)	6 (6,4)	9 (6,5)	0,978
Malignity	26 (11,2)	11 (11,7)	15 (10,8)	0,829
Congestive heart failure	29 (12,4)	10 (10,6)	19 (13,7)	0,492
Kidney failure	42 (18,0)	18 (19,1)	24 (17,3)	0,714
Coronary arter disease	26 (11,2)	14 (14,9)	12 (8,6)	0,136
Asthma/COPD	21 (9,0)	6 (6,4)	15 (10,8)	0,249
Chronic liver disease	2 (0,9)	2 (2,1)	0 (0,0)	0,056
Rheumatological diseases	8 (3,4)	4 (4,3)	4 (2,9)	0,575
Time to surgery (days)*	2 [2-4]	2 [1-4]	3 [2-4]	0,075
Number of comorbidities*	2 [1-3]	2[1-3]	2 [1-3]	0,236
Length of stay (days)*	5 [4-7]	5 [4-7]	5 [4-7]	0,908

Data are expressed as mean ± SD, or number (percentage) or \*Median [% 25-75 percentiles]. NVTA: Non-vehicle traffic accident, IVTA: In-vehicle traffic accident, DM: Diabetes Mellitus, HT: Hypertension, COPD: Chronic obstructive pulmonary disease.

PFFs over 65 years of age 50.8% were femoral neck fractures and 48.2% intertrochanteric fractures.<sup>11</sup> In our study, neck fractures were detected in 40.3% of patients and trochanteric fractures in 59.7%. The potential association between the age and type of fracture was also studied. Diaz et al.<sup>5</sup> reported no association between these variables, in contrast, some studies showed trochanteric fractures were observed more often in patients with an increased age which was also further supported in our study.<sup>2,10</sup> We don't know yet,

**Table 2.** Logistic regression analysis of variables that affect fracture type.

Variables	B	Wald	OR [95% CI]	P
Age	0,040	3,17	1,041 [0,996-1,089]	0,075
Trauma		0,382		0,933
Fall from height vs fall ground level	21,371	0,000	-	0,999
NVTA vs Fall ground level	-0,592	0,382	0,553 [0,085-3,616]	0,510
IVTA vs Fall ground level	20,196	0,000	-	0,999
In life vs Death	0,847	2,674	2,333 [0,845-6,443]	0,102
Complication Yes vs No	0,499	2,140	1,647 [0,844-3,215]	0,143
Number of comorbidities	-0,250	3,931	0,778 [0,608-0,997]	0,047
Time to surgery	0,119	1,400	1,126 [0,925-1,371]	0,237

NVTA: Non-vehicle traffic accident, IVTA: In-vehicle traffic accident.

**Table 3.** Demographic and clinical relationship of patients according to their survival status.

Variables	Dead 38 (16.3%)	Alive 195 (83,7%)	P
Age(Mean SD)	82.1 7.1	80.9 7.5	0,338
<b>Age groups</b>			<b>0,595</b>
65-74 ages	6 (15,8)	44 (22,6)	
75-84 ages	18 (47,4)	79 (40,5)	
≥85 ages	14 (36,8)	72 (36,9)	
Gender, Women	23 (60,5)	126 (64,6)	0,631
<b>Trauma mechanism</b>			<b>0,013</b>
Fall from height	2 (5,3)	2 (1,0)	
NVTA	2 (5,3)	5 (2,6)	
IVTA	2 (5,3)	0 (0,0)	
Fall ground level	32 (84,2)	188 (96,4)	
Complication	28 (73,7)	53 (27,2)	<0,001
Comorbidity	35 (92,1)	169 (86,7)	0,509
Mild comorbidity index	17 (44,7)	118 (60,5)	0,015
Moderate comorbidity index	11 (28,9)	43 (22,1)	
Severe comorbidity index	7 (18,4)	8 (4,1)	
Fracture side, Left	18 (47,4)	112 (57,4)	0,253
Fracture side , Right	20 (52,6)	83 (42,6)	
Surgical condition	28 (73,7)	156 (80,0)	0,382
Time to surgery	3 [2-4]	2 [1-4]	0,099
ASA score Moderate	1 (3,2)	38 (23,8)	0,001
ASA score High	10 (32,3)	73 (45,6)	
ASA score Highest	20 (64,5)	49 (30,6)	
Length of stay <7 days	25 (67,6)	136 (84,5)	0,017
Length of stay >7 days	12 (32,4)	25 (15,5)	
Number of comorbidities *	2 [1-3,25]	2 [1-2]	0,008
Length of stay *	6 [4-9]	5 [4-7]	0,112

Data are expressed as mean ± SD, or number (percentage) or \*Median [% 25-75 percentiles]. NVTA: Non-vehicle traffic accident, IVTA: In-vehicle traffic accident.

whether the level of osteoporosis or another possible alteration in bone morphology with increasing age influences the fracture type. According to our opinion, this is an obscure field that should be investigated. In our study, we were not able to identify any other relevant variables that may affect the type of fracture. The relation between the type of hip fracture and mortality rate is controversial. In many mortality studies, patients with trochanteric fractures were found to have a higher mortality rate than those with femoral neck fractures,<sup>2,12</sup> whereas Kim et al. reported that cervical fracture had a higher risk for mortality than trochanteric fracture<sup>13</sup> and some studies did not show an association.<sup>14,15</sup> We found that



the mortality rate after trochanteric fracture to be higher. However, this may be associated with the higher mean age of the trochanteric fracture group in our study. Similar mortality rates in patients older than 85 years old may be accepted as a supporting finding to our conjecture. Increased risk of mortality is expected with the increasing age in patients older than 65 years with hip fractures.<sup>16</sup> Nevertheless, we found that the highest mortality rate of 47.4% was in patients between 75 and 84 years old. We think that this might be associated with a higher rate of comorbidities in this group. In a mortality study of Kesmezacar et al. in patients over 65; 57.9% of 76 male patients and 41.9% of 172 female patients died. The overall mortality rates were significantly higher in men than in women.<sup>15</sup> In our study, no gender differences were found in the mortality rates.

It has been found that 82% of patients with femoral fractures have an important medical condition that contributes to or complicates the fracture.<sup>6</sup> In the study in which Diaz et al. examined the risk factors for trochanteric and femoral neck fractures, the number of comorbidities was between 5-9, 35% patients with neck fractures, and 47.1% patients with trochanteric fractures were identified. This was found statistically significant.<sup>5</sup> In a study by Fox et al. on 923 patients with proximal femur fractures over 65 years of age; 4 or more comorbid diseases were detected in 82.3% of intertrochanteric fractures and 76.1% of neck fractures.<sup>2</sup> In our study, 59.7% of patients with trochanteric fractures had 1-2 and 55.3% of patients with neck fractures had 1-2 comorbid diseases. CCI has been applied in outcome studies on elderly patients with hip fractures, and a meta-analysis revealed that the zero scores have a 41% lower risk of death compared to those with one or more CCIs.<sup>17</sup> In our study, consistent with the literature, the probability of mortality was higher in patients with high CCI score.

There are contradictory reports regarding the association of the mechanism of trauma and the localization of the fracture.<sup>8,18</sup> Our study showed no association between these variables. To classify most of the patients in a group as falls may be misleading since the different acting forces in the fracture region are not considered. In the study of mortality in the first year after the proximal femoral fracture in elderly patients, mortality increased as the ASA score increased.<sup>19</sup> Our study is compatible with the literature, and it has been determined that mortality increases with the increase in the ASA score.

The ideal time for surgical repair of hip fractures is controversial. Early surgical treatment is associated with independent return to life, shorter hospital stays, and 1-year survival rates. These studies are related to general hip fractures.<sup>20,21</sup> Nevertheless, there is insufficient data regarding the location of the fracture and its timing of the operation. In a study related to the time of surgery according to the fracture location, the average delay to surgery in patients over 65 years of age was 8.7 days for trochanteric femur fractures and 11.3 days for femoral neck fractures.<sup>15</sup> Different results have been reported in studies conducted on the effect of time to surgery on 1-year mortality in hip fractures.<sup>22,23</sup> In our study, when trochanteric and head/neck fractures were examined within themselves, the time until surgery did not affect on mortality. However, we think that

this can be caused by the operation of trochanteric fractures in an average of 3 days and neck fractures in a short time such as 2 days. In studies involving hip fractures operated later in the literature, we could not find any data showing the relationship between different types of fractures and mortality.

A previous study reported longer hospitalization duration for patients with trochanteric fractures (19.7 days) than femoral neck fractures (17.5 days).<sup>2</sup> Approximately 80% of patients with fractures were hospitalized for up to 7 days in our study. Umarji et al. reported that if patients with PFFs stay in the hospital for longer than 8 days, this would not benefit the patient since most patients get a nosocomial infection after 8 days<sup>24</sup> which was also consistent with our study. It is also highly possible that the preoperative conditions of these patients could be the reason for the longer hospitalization that eventually leads to a higher mortality rate.

The incidence of postoperative complications after hip fractures was found to be 20%.<sup>23</sup> However, the potential role of the fracture location on complications was not investigated before. In our study, 34.8% of cases developed complications after a fracture. In our study, 41% of patients developed complications after trochanteric fracture, which was considered significant. Complications were found in 73.7% of patients who died. Higher mean age and comorbidity rates in the trochanteric fracture group may be the reason for this.

Our study had several limitations. One is the retrospective nature of the study and its being single-centered. Another limitation is the possible lack of patient data through file scanning. Some variables such as Alcoholism, hyperthyroidism, or hypovitaminosis D, body mass index, and geometry of the treated hip could not be studied due to insufficient data. Further prospective studies with larger groups are needed.

## CONCLUSION

In conclusion; the majority of the patients with PFFs admitted to the ED are trochanteric fractures. Most of these patients are female and the frequency of fractures increases as the average age increases. In trochanteric fractures, fall ground level, mortality, complications, and surgical intervention are more common. There is no difference in the presence of comorbidity between both types of fractures, but in logistic regression analysis, only the number of comorbidities is effective on the fracture type. In general, fall ground level, development of complications, comorbid index, increased comorbid count, high ASA score, and length of stay are the effective factors found in patients who died due to PFF. Patients who develop complications have a higher risk of death. We believe that our findings can guide healthcare professionals and new research in terms of approach to patients applying to the ED with a proximal femur fracture.

## ACKNOWLEDGMENTS

We would like to thank Dr. Suavi Aydogmus for his revision of the article, his contributions to language editing and suggestions.

**AUTHORS' CONTRIBUTION:** Each author contributed individually and significantly to the development of this article. AK and BC: study design, writing, review, and approval of the final version; AM: review, intellectual concept of the article and approval of the final version; AK, BC and SE: data collection, analysis and interpretation, and writing; SBB and AY: review, intellectual concept of the article and approval of the final version

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# TRANSOLECRANON FRACTURE-DISLOCATION: CONCEPTS AND FUNCTIONAL RESULTS OF SURGICAL TREATMENT

## FRATURA LUXAÇÃO TRANSOLECRANIANA: CONCEITOS E RESULTADOS FUNCIONAIS DO TRATAMENTO CIRÚRGICO

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### ABSTRACT

**Objective:** This study aimed to evaluate the functional results of the treatment protocol for the treatment of transolecranon fracture-dislocation, by surgical reduction and osteosynthesis with plate and screws, in patients attended at a referral hospital for orthopedic trauma, with a minimum follow-up period of six months. **Methods:** Twenty-five individuals treated surgically from January 2014 to November 2018 were selected for a primary observational longitudinal study using questionnaires to assess upper limb and elbow function (DASH and MEPS), quality of life (SF-12), pain (visual analog scale - VAS), and radiographic evaluation in anteroposterior and lateral views of the elbow. **Results:** Fifteen patients were male, and the mean age was 46.8 years. All participants had their fractures consolidated, with no radiographic signs of implant failure, or degenerative arthritis. Mean range of motion was reduced relative to the contralateral limb: 102.6° for flexion-extension and 132.8° for pronation-supination. The mean MEPS and DASH scores were 89.6 and 16.5 respectively. There was no residual pain in 84% of the cases according to the VAS. **Conclusion:** The surgical treatment proposed for transolecranon fracture-dislocations showed satisfactory results according to MEPS, DASH scores and quality of life measures. **Evidence Level IV; Retrospective observational study.**

**Keywords:** Orthopedic Procedures; Elbow; Olecranon; Fractures, Bone; Joint Dislocations.

### RESUMO

**Objetivo:** Avaliar os resultados funcionais do protocolo de tratamento da fratura-luxação transolecraniana, por redução cirúrgica e osteossíntese com placa e parafusos, nos pacientes atendidos em hospital de referência para trauma ortopédico, com seguimento mínimo de seis meses. **Métodos:** vinte e cinco indivíduos tratados cirurgicamente de janeiro de 2014 a novembro de 2018 foram selecionados para um estudo longitudinal observacional primário, utilizando questionários para avaliar a função do membro superior e cotovelo (DASH e MEPS), qualidade de vida (SF-12), dor (visual escala analógica - EVA), e avaliação radiográfica nas incidências anteroposterior e perfil do cotovelo. **Resultados:** Quinze pacientes eram do sexo masculino e a média de idade foi de 46,8 anos. Todos os participantes tiveram suas fraturas consolidadas, sem sinais radiográficos de falha do implante ou artrite degenerativa. A amplitude média do movimento foi reduzida em relação ao membro contralateral: 102,6° para flexo-extensão e 132,8° para pronosupinação. Os escores médios de MEPS e DASH foram 89,6 e 16,5, respectivamente. Não houve dor residual em 84% dos casos de acordo com a EAV. **Conclusão:** O tratamento cirúrgico proposto para a fratura-luxação transolecraniana apresentou resultados satisfatórios de acordo com MEPS, escores DASH e medidas de qualidade de vida. **Nível de evidência IV; Estudo observacional retrospectivo.**

**Descritores:** Procedimentos Ortopédicos; Cotovelo; Olécrano; Fraturas Ósseas; Luxações articulares.

**Citation:** Mota Neto J, Cruz Neto SA, De Simoni LF, Zimmermann DSR, Andrade-Silva FB, Mendes Júnior AF. Fratura luxação transolecraniana: conceitos e resultados funcionais do tratamento cirúrgico. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 5. Available from URL: <http://www.scielo.br/aob>.

### INTRODUCTION

Elbow fracture-dislocations (EFD), although relatively common occurrences in elbow trauma (between 10 and 20%),<sup>1</sup> are considered complex and unstable injuries for treatment, especially due to the osseous and soft lesions. The objective of its treatment is to achieve a stable, painless joint with a functional range of motion.<sup>2-4</sup>

However, the functional results of this treatment varies according to the subtype of EFD.<sup>3,5,6</sup> Transolecranon fracture-dislocations (TFD) are a subgroup of EFD. They were initially described by Biga and Thomini<sup>7</sup> as a complex injury associated with high-energy trauma.<sup>7</sup> For Ring<sup>8</sup>, in TFD there is anterior translation of the forearm in relation to the distal

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Hospital Universitário da Universidade Federal de Juiz de Fora, Juiz de Fora, MG, Brazil.

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Article received on 08/25/2021, approved in 02/10/2022.



humerus, without dissociation of the proximal radioulnar, rarely injuring the radial head or annular ligament, which distinguishes it from an anterior Monteggia lesion.<sup>8</sup> O'Driscoll<sup>9</sup>, in his classification of coronoid process fractures, assigns the TFD designation as type 3.<sup>9</sup> Treatment of TFD is mainly surgical, with open reduction and internal fixation with a plate and screws,<sup>8,10</sup>, but there is a lack of standardized surgical planning and execution or post-operative rehabilitation protocol<sup>8</sup>. Nevertheless, the result is varied from good elbow function with anatomical reduction and stability after fixation,<sup>11</sup> to deficits in range of motion, progressive and disabling pain.<sup>12-14</sup> The aim of this study is to evaluate the functional outcomes of surgical treatment of TFDs in a referral hospital for orthopedic trauma, with a minimum follow-up period of six months. The authors hypothesize that the standardized treatment protocol employed produces satisfactory results and is compatible with the literature.

## MATERIAL AND METHODS

A primary, longitudinal, observational study of patients with TFD surgically treated between January 2014 and November 2018 was conducted in a referral hospital for orthopedic trauma. All procedures were performed by two orthopedic surgeons with experience in elbow trauma surgery. This research was submitted to and approved by the institution's Research Ethics Committee (CAAE: 89358318.3.0000.5103). This manuscript was written according to the STROBE guideline.

### Sample

The inclusion criteria were adults with unilateral or bilateral TFD, submitted to surgical treatment with open reduction and internal fixation with plate and screws, with a post-surgical follow-up for at least six months. Patients with a history of fractures or previous trauma to the elbow, pathological fractures, and with congenital diseases in the injured limb were excluded. Those who met the selection criteria were invited for an interview, and functional and radiographic evaluation. Those who agreed to participate in the study completed a free and informed consent form and questionnaires to assess upper limb and elbow function, quality of life, and pain measurement, in addition to radiographic evaluation of the operated elbow.

### Functional outcomes

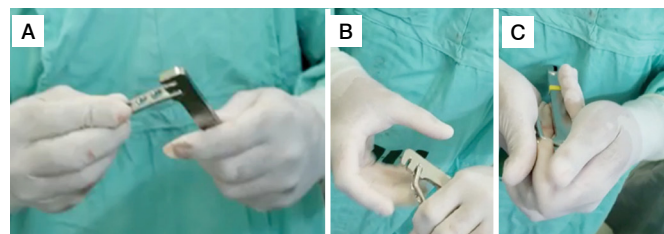
The Disability of the Arm, Shoulder and Hand (DASH) score<sup>15</sup>, which is a general upper limb assessment scale, and the Mayo Elbow Performance Score (MEPS)<sup>16</sup>, instrument for evaluation of elbow function, were used. To analyze these results in dichotomous satisfactory or unsatisfactory, the value of the minimal clinically important difference (MCID) of 10 points was used for both DASH<sup>17</sup> and MEPS<sup>18</sup>. For quality of life (QOL), the SF-12 questionnaire<sup>19</sup> was used, and following Ware's criteria<sup>20</sup> for satisfactory or unsatisfactory results, we assumed a value of 50 for the physical score (PCS) and 42 for the mental score (MCS).<sup>20</sup> The level of pain was verified using the visual analog scale (VAS).<sup>21</sup>

### Surgical technique

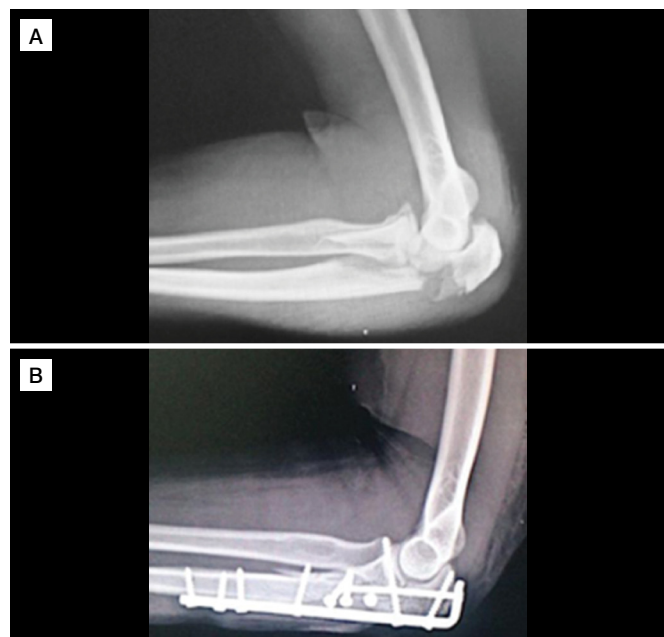
The patients were placed in a supine position with shoulder abduction of 70° and limb positioned under a radiolucent table, after regional and general anesthesia. A curved posterior incision was made around the tip of the olecranon, folding as large a fasciocutaneous flap as possible to avoid skin complications. Dissection by planes, access to the fracture with cleaning of the focus and identification of the main fragments (diaphysis, olecranon, medial and/or lateral ligament fragments) was carried out. In most cases, a 3.5mm non-locking dynamic compression plate (DCP) (Hexagon® Itapira, São Paulo), contoured intra-operatively, was used for internal

fixation (Figure 1 A, B, and C). In some patients, a pre-contoured locking plate from the same manufacturer was used.

Independently of the implant used, the reduction procedure began with the joint fragments and provisional fixation with intramedullary 2.0 mm Kirschner wires from the joint block to the main fragments. After that, an incision in the central portion of the triceps tendon for better accommodation of the implant, approximation of the plate using the intramedullary wire as a guide, fixation of the plate by the distal screw, followed by fixation of the proximal fragment, starting with the fragment of the coronoid process and a long 3.5 mm cortical screw in place of the temporary wire. Then, open reduction of the fragments and fixation with screws was performed or transosseous sutures with nonabsorbable wires (Figure 2) for the small fragments. Finally, assessment of the alignment of the fragments with an image intensifier, stress maneuvers in varus and valgus to assess stability, and range of motion of the elbow for joint protrusions. In the first postoperative day, active elbow movement orientation was encouraged, without load, according to pain limit, and use of a arm sling as necessary. Returns to the outpatient clinic were scheduled for the first 15- and 30-days post-operative, and then a monthly evaluation up to six months of follow-up. The physical therapy program was initiated after de 15<sup>th</sup> day, according to the protocol of the institution.



**Figure 1.** A, B, and C: Hexagon® 3.5 mm DCP modeling technique with the use of a contouring tool: A - Plate tip is placed on the widest part of the tool. B and C - Compression to bend the plate at the second hole to adapt the implant to the olecranon.



**Figure 2.** A and B: Pre and Postoperative radiograph of the profile views of the participant's left elbow showing transolecranon fracture-dislocation (A) and osteosynthesis with a 3.5 mm non locking compression plate, and lag screws (B).



## Assessment

The final assessment was carried out by an independent examiner, not involved in the surgical procedures, who proceeded to interview the participants to confirm demographic data, perform the physical examination with range of motion of the elbow and forearm, pain, DASH, MEPS and SF-12. Participants underwent imaging assessment with anteroposterior and lateral radiographs of the operated elbow, with analysis of consolidation or pseudoarthrosis, joint surface contours, presence of malunion or implant failure being carried out. This examiner also reviewed data from the participants' medical records about the operation and its follow-up, such as time for consolidation, presence of delayed consolidation, pseudoarthrosis, infection, and failure of synthesis material.

## Statistical analysis

Quantitative variables were described using mean and standard deviation, and qualitative variables using absolute frequency and percentages. To test for differences between the groups of patients with satisfactory or unsatisfactory results according to the MEPS scale, the Student's *t*-test was used for independent samples with parametric distribution, or the Mann-Whitney U test for non-parametric samples. To test for differences in qualitative variables between groups, Fisher's exact test was used. The effect size (clinical significance) was assessed using Cohen's *d* (quantitative variables) or Cramer's *V* (qualitative variables), using the following classification for interpretation: lower Cohen's *d*  $\leq 0.49$ ; moderate 0.50 to 0.79; high  $\geq 0.80$ ; lower Cramer's *V*  $\leq 0.29$ ; moderate 0.30 to 0.49; high  $\geq 0.50$  (Cohen, 1992). All analyses were done using IBM SPSS version 20.0 statistical software (IBM Corp., Armonk, NY). The value of  $p < 0.05$  was adopted for statistical significance.

## RESULTS

25 individuals were included for clinical and radiographic evaluation. Most were male (60%), the mean age was 46.8 years (ranging from 21 to 89 years) (Table 1). The dominant side was affected in 40% of the cases, the mean time until surgery was eight days (ranging from 2 to 20 days), and the mean follow-up time was 25 months (ranging from 6 to 62 months). In twenty patients, a 3.5 mm Hexagon® non-locking compression plate was used. Another

five individuals underwent ORIF with a pre-contoured Hexagon® plate. Regarding the associated procedures, in one case, an autologous bone graft (from the iliac) in the olecranon and fixation with a mini-micro fragment screw was used; seven patients had fractures of the radial head, of which one case was treated with resection of the fragment, due to its small size, in two cases ORIF of the radius was performed with 2.4mm lag screws, and in four cases arthroplasty of the radial head was performed. In one case, transosseous suture of the medial collateral ligament (MCL) was performed. Radiographic analysis showed consolidation in all cases, with no loosening, implant failure, or signs of degenerative arthritis. There was no radiographic difference between patients who used non-locking or pre-contoured implants.

In the functional analysis, 16 patients (68%) had excellent MEPS. (Figure 3) The MEPS results were divided into two groups: satisfactory (patients with good or excellent results) and unsatisfactory (poor, bad, and regular results). The same methodology was used for the DASH. According to this criterion, through the MEPS, 21 patients (84%) presented satisfactory results and, according to the DASH, 17 patients (68%). Table 1 shows the comparative results between patients who presented satisfactory versus unsatisfactory MEPS and DASH. The groups were similar in terms of age, sex, affected side, presence of associated fracture, presence of comorbidities, type of implant, time until surgery, and follow-up time ( $p > 0.05$ ). However, patients with satisfactory MEPS were younger, with trend

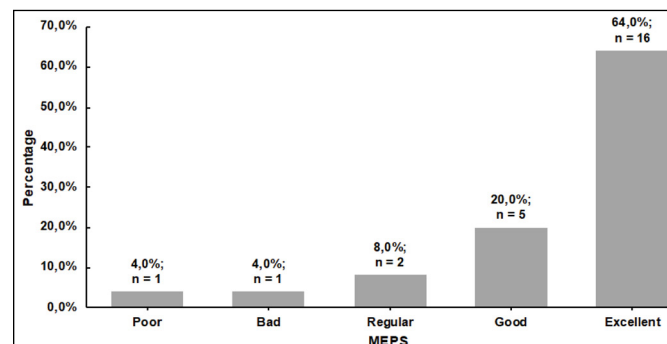


Figure 3. Distribution of functional results according to MEPS score.

Table 1. Comparison of characteristics of patients with transolecranon fracture-dislocation, according to the MEPS and DASH.

Factor	All (n=25)	MEPS		p-value	(ES)	DASH		p-value	ES
		Satisfactory (n= 21)	Unsatisfactory (n=4)			Satisfactory (n= 17)	Unsatisfactory (n=8)		
Age (years)	46.9 ± 17.7	49.4 ± 17.5	33.7 ± 13.7	0.11	1.01	45.3 ± 17.5		0.54	0.26
Sex									
Male	15 (60.0%)	13 (86.7%)	2 (13.3%)	1.00	0.10	12 (80.0%)	3 (20.0%)	0.19	0.31
Female	10 (40.0%)	8 (80.0%)	2 (20.0%)			5 (50.0%)	5 (50.0%)		
Affected side									
Left	15 (60.0%)	13 (86.7%)	2 (13.3%)	1.00	0.10	9 (60.0%)	6 (40.0%)	0.40	0.21
Right	10 (40.0%)	8 (80.0%)	2 (20.0%)			8 (80.0%)	2 (20.0%)		
Associated Injury/Fracture									
Yes	9 (36.0%)	7 (77.8%)	2 (22.2%)	0.60	0.13	5 (55.6%)	4 (44.4%)	0.39	0.20
No	16 (64.0%)	14 (87.5%)	2 (12.5%)			12 (75.0%)	4 (25.0%)		
Implant Type									
Compression Plate	20 (80.0%)	16 (80.0%)	4 (20.0%)	1.00	0.22	14 (70.0%)	6 (30.0 %)	1.00	0.09
Locking Plate	5 (20.0%)	5 (100.0%)	0 (0.0%)			3 (60.0%)	2 (40.0%)		
Comorbidities									
Yes	8 (32.0%)	6 (75.0%)	2 (25.0%)	0.57	0.17	4 (50.0%)	4 (50.0%)	0.36	0.26
No	17 (68.0%)	15 (88.2%)	2 (11.8%)			13 (76.5%)	4 (23.5%)		
Time until surgery (days)	8.0 5.0	8.0 6.0	6.0 5.0	0.61	0.36	9.0 6.0	5.0 4.0	0.11	0.80
Follow-up time (months)	25.0 15.0	26.0 15.0	16.0 11.0	0.19	0.77	26.0 13.0	23.0 19.0	0.65	0.19

(P values calculated using Student's *t* test for quantitative variables and Fisher's Exact test for qualitative variables; percentages refer to the lines; ES = effect size).

to statistical significance ( $p = 0.11$ ) and an effect size that suggests a relevant clinical difference for this variable. The TFD subgroup analysis between patients with or without radio head fractures or associated injuries demonstrated that there were no statistically significant differences between the physical exam, MEPS, or DASH variables. Table 2 presents the clinical, functional, and quality of life results of the overall sample and of the patients divided according to MEPS and DASH. Patients with satisfactory MEPS showed greater extension, flexion-extension arc, lower DASH, and greater SF-12 PCS ( $p < 0.05$ ). Most patients with VAS  $> 0$  were classified as unsatisfactory MEPS. Whereas the results found in relation to the DASH were not statistically significant for clinical, functional, and quality of life outcomes, except for the physical component of the SF-12.

## DISCUSSION

Our data analysis state that despite the complexity of the transolecranon fracture-dislocation (TFD), the average results with this standardized surgical treatment applied were satisfactory according to the functional scores. Also, in the analyzed sample, a younger age profile was observed among those with better functional results. These results are in line with the literature reports that of the surgical treatment of TFD are effective in restoring elbow congruity, but individuals generally present some functional deficit.<sup>13,14</sup> Mortavizi<sup>12</sup>, assessing eight patients with TFD, reported satisfactory results in seven cases, according to the Morrey score. Niéto<sup>22</sup>, in an assessment of 11 cases of TFD, described a mean functional result of 70, according to the same score.<sup>22</sup> In our sample, satisfactory results were observed in a larger number of cases (21 individuals). Mouhsine<sup>13</sup>, evaluating the surgical treatment of 14 patients with TFD, seven fixed with Kirschner wire and tension band, seven others with plate and screws (1/3 tubular, DCP or reconstruction), reported ten (71%) satisfactory results according to the Morrey score, and four cases of radiographic signs of degenerative arthritis in the x-ray exams.<sup>13</sup> All the individuals described in our study were submitted to the same surgical protocol, and in 20 of them were used the same plate, bended with the same technique. Also, no signs of degenerative arthritis were observed, which might strengthen the standardized treatment.

Although the complex clinical presentation of TFD, no patient in our study presented clinical or radiographic instability after the applied treatment protocol. Moreover, in only one of 25 individuals a

transosseous suture for medial collateral ligament was performed which raises doubts about whether TFD has its instability related to a mixed pattern of bone and ligament injury or whether the instability is mainly from the multifragmented pattern of the articular fracture, that compromises the sites of ligament insertion. According to Siebenlist<sup>10</sup>, the treatment of TFD should be based on the principle of stable fixation with plate and screws, given the comminuted nature of the fractures.<sup>10</sup> In this sense, the standardization of bone fixation leading to stability, as demonstrated in the cases evaluated, strengthens the thesis of instability due to bone injury than soft tissue injury.

Satisfactory results were found in both the specific elbow, overall upper limb and quality of life scores. This is in line with the literature on the treatment of TFD as satisfactory, with a favorable prognosis and low incidence of complications.<sup>12,22</sup> Bailey et al<sup>23</sup>, analyzing the results of the surgical treatment of displaced and comminuted fractures of the olecranon in eleven patients, reported that 45% of them presented "excellent" MEPS scores.<sup>23</sup> The results reported in our sample demonstrate that, according to the same evaluation, a higher percentage (64%) of excellent results were observed.

Yet, in the analysis of pain, the major percentage of the sample (84%) had a VAS of zero, coinciding with the study by Bailey et al.<sup>23</sup> that found the majority of their sample without reference to pain in the evaluation. Nevertheless, mean values for the physical component of the SF-12 of 48.1 (SD 9.7) were observed, similar to that described by Bailey, who using the SF-36, found mean values of 48 (SD 12).<sup>23</sup> However this author did not differentiate the quality of life measure between the functional results, unlike this sample, in which it was observed that individuals with unsatisfactory MEPS have an association with lower SF-12 PCS values, which reflects the impact of the physical alteration on an aspect of quality of life. Surgical treatment of TFD with a multiple choice of implants may lead the need for revision surgery. Ring<sup>8</sup> stated that, of his series of 17 patients, the two fixed with a 1/3 tubular plate, required revision for osteosynthesis with 3.5 mm DCP. Mortavizi<sup>12</sup> reports that a case fixed with a tension band with Kirschner wire required revision for fixation with DCP.<sup>12</sup> Mouhsine<sup>13</sup> also reports that the use of wire fixation in the TFD required revision to fixation with plate and screws.<sup>13</sup> Our results demonstrate that all TFD were treated according to the same protocol, and no need for post-operative revision was observed. Some limitations might be underscored in this study. The small sample size is related to the low incidence of TFD, it might

**Table 2.** Comparison of clinical, functional, and quality of life results of patients with transolecranon fracture-dislocation, according to the MEPS and DASH.

Factor	All (n = 25)	MEPS		p	ES	DASH		p	ES
		Satisfactory (n= 21)	Unsatisfactory (n=4)			Satisfactory (n= 17)	Unsatisfactory (n=8)		
VAS 0 ≥1	21 (84.0%) 4 (16.0%)	20 (95.2%) 1 (25.0%)	(4.8%) 3 (75.0%)	0.007*	0.70	16 (76.2%) 1 (25.0%)	5 (23.8%) 3 (75.0%)	0.08	0.40
SF-12									
MCS	45.5 ± 8.8	45.4 ± 9.1	45.6 ± 8.1	0.98	0.02	44.6 ± 8.8	47.2 ± 8.9	0.52	0.29
PCS	48.1 ± 9.7	50.4 ± 8.1	35.9 ± 8.7	0.003*	1.73	53.1 ± 5.3	37.4 ± 8.2	<0.001*	2.33
MEPS	89.6 ± 14.8	-	-	-	-	95.3 ± 8.9	77.5 ± 18.1	0.028*	1.32
DASH	16.5 ± 21.5	12.8 ± 19.5	35.8 ± 24.1	0.048*	1.06	-	-	-	-
Flexion ROM	126.4° ± 15.1°	127.6° ± 14.6°	120.0° ± 18.2°	0.37	0.46	129.4° ± 15.3°	120.0° ± 13.4°	0.15	0.66
Extension ROM	-23.8° ± 21.9°	-17.8° ± 15.5°	-55.0° ± 26.4°	0.001*	1.78	-19.1° ± 17.1°	-33.7° ± 28.6°	0.21	0.64
Flexo-Extension ROM	102.6° ± 33.2°	109.8° ± 26.3°	65.0° ± 44.3°	0.01*	1.27	110.3° ± 27.5°	86.2° ± 40.0°	0.09	0.82
Pronation ROM	64.8° ± 14.7°	69.0° ± 8.3°	42.5° ± 22.1°	0.09	1.74	68.8° ± 9.2°	56.2° ± 20.6°	0.14	0.85
Supination ROM	68.0° ± 13.5°	67.1° ± 14.5°	72.5° ± 5.0°	0.48	0.55	70.0° ± 6.1°	63.7° ± 22.6°	0.47	0.44
Prone-Supination ROM	132.8° ± 17.7°	136.2° ± 15.3°	115.0° ± 20.8°	0.02*	1.17	138.8° ± 8.6°	120.0° ± 25.0°	0.07	1.12

(VAS: Visual Analog Pain Scale; SF12: Quality of life; p values calculated using Student's t test for quantitative variables and Fisher's Exact test for qualitative variables; ES = effect size).

compromise the comparison between locking and non-locking implants. The sample size, however, was similar to or greater than other studies in the literature.<sup>8,11-13</sup> About the strenght aspects of our study, that the evaluation of a homogeneous sample with a low-incidence fracture, treated with the same protocol in all cases, resulted in satisfactory functional results, reinforcing the internal validity of the treatment used. Also, the low demand for osteoligamentary fixations with elbow stability in the follow-up,

reinforces the theory of TFD's instability due to bone involvement, instead of soft tissues injuries.

## CONCLUSION

Surgical treatment of TFD by a standardized treatment protocol with open reduction and internal fixation with plate led to satisfactory functional results in most cases, without residual pain, and low interference in the quality of life of the patients.

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**AUTHORS' CONTRIBUTION:** Each author made significant individual contributions to the development of this manuscript. JMN: concept and design of work, writing and performing surgeries; SACN: data analysis and writing of the work; LFS: concept, design of work, and performing surgeries; DSRZ: data analysis and writing of the work; FBAS: critical review of the article and final approval of the manuscript; AFMJ: intellectual concept of the article, critical review of the article, final approval of the manuscript.

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# THE CEMENTED DOUBLE MOBILITY CUP IN HIP REVISION: DIFFERENT POSSIBILITIES OF USE

## ACETÁBULO CIMENTADO DE DUPLA MOBILIDADE EM REVISÃO DE QUADRIL: DISTINTAS POSSIBILIDADES DE USO

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### ABSTRACT

**Introduction:** The aim of our work is to review those patients who underwent prosthetic hip revision surgery in our hospital considered to be patients at high risk of dislocation or recurrent dislocation, and who underwent a double mobility cemented cup (CMD). Analyzing the different ways to place these cups and the clinical results and relaxations. **Material and methods:** The 69 cases comprised 34 men and 35 women with a mean age of 77,39 years. The mean follow-up was 4.7536 years. The type of intervention performed varied according to the cause of the intervention, the acetabular bone stock and the state of the primary cup. In the cases in which there was a good fixation of the primary metalback, we opted to carry out a cementation of the cemented DMC into the existing well-fixed metal acetabular shell, this occurred in 23 cases. In the cases where there was loosening of the primary cup but there was a good bone stock, a CMD was cemented into the bone (21 cases). In the cases where there was a Paprosky type III we cemented a DMC to a Bursch-Schneider reinforcement ring together with the placement of a cancellous bone graft (25 cases). **Results:** The clinical evaluation at the end of the follow-up, according to the MD Scale, showed the mean value was 16.454 (SD 0.79472), with a survival at the end of the follow-up of 100% of the placed DMC. **Conclusion:** The use of cemented DMC is a good solution in the replacement of THA, especially in cases of relaxation or risk of dislocation due to personal or technical predisposing factors. The use of these DMC cemented can be directly to the bone, into the existing well-fixed metal Shell, or cemented to a reinforcing ring, depending on the acetabular defect. **Evidence Level III; Comparative Case Series.**

**Keywords:** Reoperation, Procedures, Operative Surgical, Hip Replacement, Total, Follow-Up Studies.

### RESUMO

**Introdução:** Revisar os pacientes que foram submetidos à cirurgia de revisão protética de quadril neste hospital, considerados como pacientes com alto risco de luxação ou luxação recorrente, submetidos a cirurgia por acetábulo cimentado de dupla mobilidade (CMD). Analisando as diferentes formas de posicionamento desses copos, seus resultados clínicos e relaxações. **Material e métodos:** Os 69 casos correspondiam a 34 homens e 35 mulheres com uma idade média de 77,39 anos. O tempo médio de acompanhamento foi de 4,7536 anos. O tipo de intervenção realizada variou de acordo com a causa da intervenção, o estoque ósseo acetabular e o estado do copo primário. Nos casos em que houve uma boa fixação do metal primário, optou-se por realizar uma cimentação do DMC cimentado na cúpula acetabular metálica firme existente, o que ocorreu em 23 casos. Nos casos em que houve um afrouxamento acetabular primário com um bom estoque ósseo disponível, cimentou-se um CMD (21 caixas). Nos casos em que havia um Paprosky tipo III, cimentou-se um DMC a um anel de reforço Bursch-Schneider juntamente com a colocação de um enxerto ósseo esponjoso (25 caixas). **Resultados:** A avaliação clínica realizada no final do acompanhamento, de acordo com a Escala MD, mostrou que o valor médio foi de 16,454 (DP 0,79472), com uma sobrevivência ao final do acompanhamento de 100% do DMC inserido. **Conclusão:** O uso do DMC cimentado pode ser uma boa solução para substituição do THA, especialmente em casos de relaxação ou risco de deslocamento devido a fatores de predisposição pessoais ou técnicos. O uso destes DMC cimentados pode ser realizado diretamente ao osso, dentro da cúpula metálica fixa existente, ou cimentados a um anel de reforço, dependendo do defeito acetabular. **Nível de Evidência III; Série de Casos Comparativos.**

**Descritores:** Reoperação, Procedimentos Cirúrgicos Operatórios, Artroplastia Total do Quadril, Seguimentos.

**Citation:** Morales de Cano JJ, Trias E. The cemented double mobility cup in hip revision: different possibilities of use. Acta Ortop Bras. [online]. 2023;31(1)Esp.: Page 1 of 5. Available from URL: <http://www.scielo.br/aob>.

All authors declare no potential conflict of interest related to this article.

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Article received on 10/02/2021, approved in 02/10/2022.





## INTRODUCTION

One of the most important complications in prosthetic hip surgery is dislocation. According to Woolson,<sup>1</sup> the incidence found in their series reaches 3.5% of the 10,500 cases of primary total hip replacement (THA) that they collect. But this incidence is much higher in revision surgery. Grigoris finds up to 25% of dislocations in the review.<sup>2</sup> According to the 2019 US THA registry, in 2017 the main reason for revision was due to prosthetic instability and in 2018 it was the second after infection.<sup>3</sup>

Rowan recently conducted a literary search to assess historical perspectives and current strategies to prevent dislocation after primary THA. This study included 3,458 articles and included 154 in its analysis.<sup>4</sup> There are two groups of causes that can favor prosthetic instability and therefore dislocation: patient-specific causes and technical causes. Among the patient's own causes, it has been shown that age, body mass index above 30Kg / m<sup>2</sup>, lumbosacral pathology, rheumatoid arthritis, muscle atrophy, history of interventions on the same hip, can be factors favoring instability. Among the technical causes, the approach route, the size of the femoral heads, the anteversion of the cotyloid component, the inclination of the acetabular component, the relaxation of the soft tissues, the femoral retroversion. Taking into account all the favorable effects of prosthetic instability, preoperative planning is very important in a primary THA, but much more in revision surgery. It is also important to be able to do a dynamic test with the trial prosthetic components during surgery, such as the push-pull test, to assess the soft tissue tension and the stability of the prosthesis. But not all approaches facilitate it in the same way.<sup>4,5</sup>

In these circumstances, any technical help that can improve the stability of the surgery and especially in revision surgery, is welcome. In revision surgery, patients already have a history of surgeries with poorer quality soft tissue and many times with bone defects that are difficult to resolve. There is no doubt that double mobility cups (DMC) have become an aid to improve stability. Good results have been reported in the use of DMC in primary surgery,<sup>6,7</sup> also in patients with neuromuscular problems<sup>8-13</sup> and even in revision surgery,<sup>14-16</sup> but there are still no conclusive data on the use of DMC in revision surgery. in patients with a neurological history, or older patients. The aim of our work is to review those patients who underwent prosthetic hip revision surgery in our hospital considered to be patients at high risk of dislocation or recurrent dislocation, and who underwent a cemented CMD. Analyzing the different ways to place these cups and the clinical results and relaxations.

## MATERIAL AND METHODS

In total, 69 patients underwent was operated between January 2010 and December 2001, placing an Advantage® DM cemented Shell (Zimmer Biomet, Warsaw, USA). the study was conducted in line with the established ethical guidelines of the hospital: each patient at the hospital was asked to sign an informed consent whether to let his or her data public or private for future access, and only open access medical records were reviewed by the authors of the study. Since this is an observational retrospective study, it does not describe experimental studies on either humans or animals and so it does not need any ethical approval.

The external surface of the cemented Advantage Reload metal shell has a bright polish (Ra max 0.4 µm), and the inner articulate surface is highly polished. In all cases, a cobalt-chrome femoral head was used. The diameter of the heads depended on the size of DMC used. Highly cross-linked polyethylene liner infused with vitamin E (GUR 1050) was used on all cups.

All patients were operated on by 2 highly experienced orthopedic hip surgeons. Cefazolin 2gr was administered intravenously before

surgery and twice after the operation with an interval of 8 hours. The patients underwent antero-external or posterolateral surgery and received the same rehabilitation program, which allowed full loading immediately after surgery. Thromboembolic prophylaxis with low molecular weight heparin was performed, and blood saving protocol with tranexamic acid. In the postoperative period, surgical bleeding and days of hospital admission were analyzed. The indications for these implants in particular were: patients without age limits who require revision surgery due to implant instability, or revision surgery with their own or technical risk factors for prosthetic instability. All cases were submitted to preoperative planning.

The 69 cases comprised 34 men and 35 women with a mean age of 77,39 years (range between 46 and 89 years) at the time of surgery. The mean follow-up was 4.7536 years (SD 2.075) between 3-16 years. The mean time elapsed between primary surgery and revision was 12.79 years (SD 6.7814) between 1-28 years. The mean body mass index was 27.40 kg / m<sup>2</sup> (range 17.38 to 43.40). The distribution of patients according to diagnosis was: in 23 cases a recurrent prosthetic instability, in 35 cases a prosthetic loosening with risk of instability, in 7 cases they were due to prosthetic replacement caused by a Vancouver type B or C periprosthetic fracture, and in 4 cases septic exchange with risk of dislocation. (Table 1) The type of intervention performed varied according to the cause of the intervention, the acetabular bone stock and the state of the primary cup. In the cases in which there was a good fixation of the primary metalback, we opted to carry out a cementation of the cemented DMC into the existing well-fixed metal Shell (Figure 1), this occurred in 23 cases. In the cases where there was loosening of the primary cup but there was a good bone stock, a DMC was cemented into the bone, this happened in 21 cases. (Figure 2) And in cases where there was a Paprosky type III A or B bone defect, we cemented a DMC to a Bursch-Schneider reinforcement ring together with placement of a cancellous bone graft in 25 cases. (Figure 3) Patients were clinically assessed using the Merle d'Aubigné (MD) score preoperatively and at the end of follow-up. The mean pre-operative assessment was 6.9276 (SD 2.068669). The radiological evaluation was carried out by means of a standard anteroposterior radiography of the pelvis and lateral hip, verifying the migration,

**Table 1.** Description of the re-revised study population.

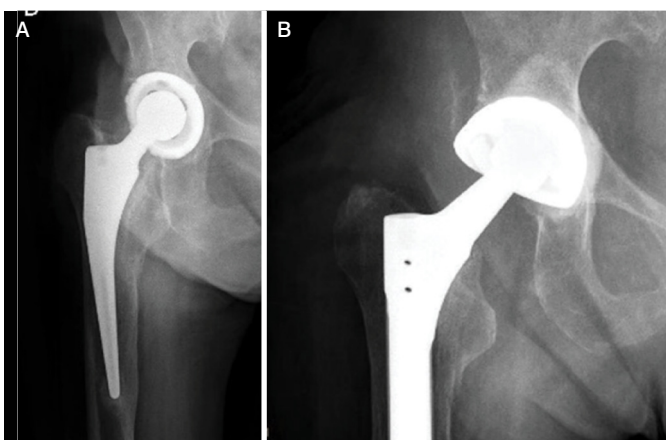
		Statistical significance
Age, years, mean (range)	77, 39 (46-89) SD 9.4217	
Sex	Female 35, male 34	P>0.005
Side, Right/Left	R 42, L 27	
Body mass index, kg/m <sup>2</sup> , mean (range)	27,40 kg / m <sup>2</sup> (range de 17,38 a 43,40)	
Operations Previous	2,3 (1-4) SD 6,7814	
Years since the first Operation	12,79 (1-28)	
Preoperative MD	6.9276 (SD 2.068669)	
Cause Surgery	-Loosening 35 cases -Dislocation recurrent 23 cases -Fractura periprotetica 7 cases -Infection 4 cases	P>0.005
Type Surgery	-Anillo Bursch-Schneider + ingerto + Cemented DMC 25 cases -Cemented DMC in metalback 23 cases -Cemented DMC in boone 21cases	P>0.005
Follow-up	4,7536 years (SD 2.075)	
MD postop	16.454 (SD 0,79472)	

osteolysis and signs of radiolucency, as well as the position of the cup and the position of the femoral stem.

Descriptive data are presented as median and range or by mean and standard deviation. The level of significance for all the analyzes performed was established at  $p \leq 0.05$ . Statistical analyzes were performed using SPSS 26.0 (SPP Inc., Chicago, IL, USA).



**Figure 1.** The case of an 86-year-old woman operated on for right PTC infection, with replacement of both prosthetic components. Placement of cemented DMC to the bone.



**Figure 2.** The case of a 79-year-old man with septic loosening of total hip arthroplasty (A). Placement of cemented DMC into DMC into the existing well-fixed metal shell (B).



**Figure 3.** The case of an 82-year-old woman with aseptic acetabular loosening. Placement of cemented DMC into the Bursch-Schneider ring.

## RESULTS

We had no intraoperative complications. In the postoperative period, a mean bleeding in the drainage of 275cc (between 225-700cc) was registered. Only 6 cases (8.69%) required transfusion. The mean hospital stay was 6.5 days (range 5-7 days). The patients began sitting 24 hours after the intervention and walking with partial load between 24-48 hours after the intervention. In the moment of hospital discharge, according to our hospital protocol, 51 patients followed the Home Hospitalization protocol with the assistance of a physiotherapist at home for the first week, 17 patients were transferred to a social health center for recovery.

As postoperative complications, we had an early infection that required debridement surgery and it resolved. We also had a case of femoral nerve paresis that resolved in 6 months. We did not have any case of venous thrombosis and we did not have any case of dislocation until the end of the follow-up.

The clinical evaluation at the end of the follow-up, according to the MD Scale, showed the mean value was 16.454 (SD 0.79472), with a survival at the end of the follow-up of 100% of the placed DMC. The radiographic evaluation at the end of the follow-up showed no subsidence of the femoral stems, there was no osteolysis, no periprosthetic ossification or radiolucency. The average acetabular inclination was 44 ° (range 42 ° - 50 °).

## DISCUSSION

Above all, we are aware of the limitations of our work due to the number of cases we present and the follow-up time of these patients. Nevertheless, we believe that it is important to analyze the results of the use of cemented DMC in prosthetic revision surgery with its possible applications.

Recurrent instability remains a difficult problem after THA revision with a recent study reporting a 35% relaxation rate after THA revision due to instability at 15 years.<sup>1,2</sup> These patients are usually elderly people who have undergone hip surgery several times and who usually have multiple underlying pathologies associated with it.<sup>4,5</sup> All this means that they can be considered high-risk patients in revision surgery. In our series, the mean age of revision surgery was 77.39 years (range 46 to 89 years). As a medical history, we have: hip reoperation patients, diabetes mellitus, hypertension, obesity, neuromuscular diseases, heart disease.

The objective of primary hip surgery is to restore the original anatomy and biomechanics of the hip by placing a THA.<sup>17</sup> For this reason, good preoperative planning is always advised through the use of templates. However, in revision surgery, preoperative planning must be more careful, it must include the evaluation of the soft tissues, especially the abductor muscles, the bone stock and its condition, knowing well the technical possibilities that we have, and above all it is very surgeon's experience is important.<sup>17</sup>

Today we have different resources in revision surgery. Hailer conducted a study of the Swedish Registry of Hip Arthroplasty between 2005 and 2010 and reported 399 revision procedures for THA due to dislocation, being more frequent in the posterior approach than the lateral or anterior approaches.<sup>18</sup> Another important factor, which we have already mentioned, is the tension of the abductor muscles.<sup>19</sup> We know that we can modify it by lateralizing the femur with the lateralized offset stems or with the larger diameter heads.<sup>18</sup> For this reason, it is advisable to change both prosthetic components at the time of THA revision surgery. But on many occasions it is difficult for the surgeon to change a component that is not loose due to the danger of associated bone fractures. In acetabular bone defects, the placement of jumbo-type acetabular components has been proposed, successfully reported in some studies,<sup>19</sup> the use of support rings associated with allograft placement,<sup>20,21</sup> the use of

large diameter has helped a lot in revision surgery.<sup>22</sup> But we know that these heads increase torsional forces at the junction of the trunion and the heads and can cause adverse local alterations, in addition to being an important cause of postoperative pain.<sup>22,23</sup> Despite all these technical aids, we need something more in revision surgery in elderly patients at risk of dislocation. We agree with Chalmers that surgical options are limited and the use of restricted liners is indicated in THA revision surgery.<sup>16</sup> Increased polyethylenes were initially used in one area of the rim, but have proven to be insufficient. Constrained polyethylenes later appeared, but they have also caused problems.<sup>24</sup> We currently have the DMC. They began to be used in the 1970s in primary THA surgery with great success.<sup>8</sup> Currently we have cemented DMC that allow us different possibilities of use. We can cement them directly to the bone in those cases where there is a good bone stock. We can also cement the DMC into the existing well-fixed metal shell in order to shorten the operative time, and reduce blood loss, bone damage, and overall perioperative morbidity.<sup>25</sup> And finally, we can cement them to a ring in cases of significant Paprosky type III A and B bone defects, associated if necessary with bone allograft for regeneration of bone defects. In our series, 25 cases were placed with a cemented DMC with a Bursch-Sneider ring associated with allograft placement; in 23 cases a DMC was cemented into the existing well-fixed metal Shell; and in 21 cases it was decided to cement the DMC directly to the bone.

One of the objectives of our work is to assess the clinical situation of the patients after the THA revision intervention with the DMC. There are many studies that recognize a good result in the assessment scales in the follow-up of these patients. Philippon recognizes a clinical improvement from 7.1 preoperatively to 15.8 10 years after the intervention according to the MD scale.<sup>26</sup> More recently, Lamo-espinosa et al. Report a mean preoperative MD score of 10.31 that goes to 15.61 postoperatively in patients undergoing THA revision using the DMC.<sup>10</sup> In a series of 36 patients considered high risk and submitted to THA revision, Plummer<sup>27</sup> reported an improved Harris Hip Score by a mean of 45 points with a final mean of 90. In our series we have gone from a preoperative assessment of 8.34, according to the MD scale, to a result at the end of the follow-up of 15.55 (Table 1). With these results we can affirm that the DMC used in the THA review can reliably improve pain and gait in these patients.

Another objective of our study is to assess re-dislocations in patients with DMC after THA revision surgery. Simian<sup>28</sup> reported a dislocation

rate of 1.4% in patients undergoing THA revision, mainly for aseptic loosening and no history of hip instability, with DMC constructions. In a 994 review THA study for all indications, Wegryzn reported a total dislocation rate of 1.5% and the intraprosthetic dislocation rate was 0.2%.<sup>29</sup> Several reports indicate up to a 30% dislocation rate of acetabular constrainer liner in operated patients at high risk of recurrent dislocation.<sup>30,31</sup> DMC constructions and restrained liners have different mechanisms for imparting hip stability. In theory, restricted liners restrict the hip to fit prosthetic design in an attempt to compensate for poor soft tissue. In our series we did not have any case of dislocation after review with the CMD in any of the operated groups.

Another of the possible advantages of the DMC is the possibility of the reduction under closed sky when there is a dislocation of the same. We have already commented previously that in many cases there is a concurrence of several instability factors that facilitate recurrent dislocation. Some of these factors can be unpredictable. This is what happens when the existence of neuromuscular diseases and abductor insufficiency of the hip are associated. Sonohata reported a case of dislocation of a line acetabular constrainer cup that was conservatively resolved without the need for surgical intervention,<sup>32</sup> but most constrainer liners have a broken mechanism and make conservative reduction impossible. However, DMC can be carried out on many occasions a conservative reduction.<sup>16</sup> But this is not always possible, as reported by Plummer, who reported two DMC dislocations in a series of 36 patients that required surgical intervention at two years of follow-up.<sup>27</sup>

In patients at high risk of dislocation despite multiple unsuccessful surgical attempts to obtain a stable hip replacement, DMC constructions not only allow greater stability, but also allow the option of treating repeated dislocations with closed reduction and braces instead of needing urgent surgical intervention as usual. the case in most dislocated constricted liners.

## CONCLUSION

As a conclusion to our work, we can affirm that the use of cemented DMC is a good solution in the replacement of THA, especially in cases of relaxation or risk of dislocation due to personal or technical predisposing factors. The use of these cemented DMC can be directly to the bone, into the existing well-fixed metal Shell, or cemented to a reinforcing ring, depending on the acetabular defect. In any case, we need more casuistry and a longer follow-up time.

**AUTHORS' CONTRIBUTION:** JJMC: Formal analysis; Investigation; Methodology; Project administration; review & editing. ET: Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Visualization; Roles/Writing – original draft; Writing.

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